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FROM THE EDITOR'S DESK

From the Editor's Desk

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On October 25, 1965, one of the world's ambassadors of peace gave a special presentation to the United Nations Assembly on the 20th anniversary of its founding. During his invited keynote, Giovanni Battista Montini spoke with particular passion about the mission of the United Nations to promote peace, and counter every force that could result in war. His words still ring within our ears: *"Jamais plus la guerre. Jamais plus la guerre."* Never again war! War, never again! The years since that moving presentation clearly give evidence that our world needs continually to hear those words and strive ever more strongly to make them a reality.

In this year, we have another important anniversary, the 80th year of remembrance of the start of the infamous syphilis studies perpetrated on the citizens of Tuskegee, Alabama. This anniversary takes place notably in the light of the recent 2009–2010 revelations of even worse unethical abuses done by the same personnel on vulnerable citizens of Guatemala. Especially given civilization's rightful upholding of law and social order for the human good, we wonder how such events could have happened. What forces are there deep within society, within culture, or within individuals that could allow such things to occur? What is it within the human self that can aspire to ethics, and yet permit the conduct of experiments and studies that are anything but ethical?

The ethical struggle with these questions is critically important. In this anniversary year, it would be easy to hang our heads in shame over the atrocities done in the Holocaust, or Tuskegee, or Guatemala. Yet the value of guilt and shame can be fleeting. While expressing our communal sorrow over the past, it is essential that we go forward such that these tragedies never happen again. Indeed, to prevent the worst it is important to promote the best.

This edition of the *Journal of Healthcare, Science and the Humanities* does just that. It seeks to promote the very best. In diverse ways, the articles published in this edition address the tragedies of the last century. Yet the authors do far more than recount history. The content they present move us to aspire more deeply to the very finest that is being done today to secure and promote the dignity and goodness of each human being in our world. The articles to follow are representative of the highest "ethos" of respect for human nature that we promote today in healthcare, the medical sciences, the healthcare humanities, and all of the disciplines of inquiry that touch upon the experience of being human. Our edition begins importantly with an introductory message from our new Navy Surgeon General,

Vice Admiral Matthew L. Nathan. It then progresses to a very special *Prelude* written by Dr. Rueben Warren, Director of the National Center for Bioethics in Research and Health Care at Tuskegee University. After Dr. Warren's *Prelude*, a wide variety of articles, commentaries and reviews invite us to consider from richly diverse disciplines all of the ways that each of us can protect and promote the utter dignity, even sacredness, of our human nature and the right of every woman, man and child to life, liberty and the pursuit of happiness.

In the history of human research protections, there were some in past decades that believed that the horrors of the Holocaust were something that occurred "back then" and "over there." We know differently today. We know that the origins of the Holocaust were not in political might or ideology. They are deeper than that. They find their origin in the horrific temptation to power, domination, arrogance, and hate. Those are the same forces that lead to war. And with Montini, we can echo today with his same passion: *"Holocaust, never again. Never again a Holocaust of any kind."*

It is to this passion that this edition of the *Journal* is dedicated. May what you are about to read fan the flames of your own passion to protect each other always, and especially to defend those who cannot defend themselves.


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SURGEON GENERAL'S MESSAGE

A Message from the Surgeon General of the United States Navy

Matthew L. Nathan, MD, FACP

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Washington, DC, USA

Note: The opinions expressed below are those of the author and do not represent the views of the Department of the Navy, the Department of Defense, or the United States Government

Over the entire course of our history, Navy Medicine has developed and maintained an abiding mission of healthcare leadership, readiness, and healing to those we are privileged to serve. We have, without faltering, faithfully been at the leading edge of serving the needs of our service members, their families, our retirees, and the unlimited numbers of women, men and children who call out to us from around the globe for humanitarian assistance and disaster relief. In short, we have developed an enduring sense of presence to those who suffer and come to us for care and understanding.

In November 2011, I was privileged to assume the leadership of Navy Medicine as the 37th Surgeon General. I am proud and humbled to be at the helm of this 63,000 person organization; and, though numerous challenges abound, I sleep better at night given the leadership team I recently inherited and where I know we are going to go together.

This calendar year of 2012 holds up a critical reminder of the responsibility of what it is we do as healthcare leaders and providers. Eighty years ago, the tragedy of the syphilis experiments in Tuskegee began. We know the history well. There are no words that can ever right that which transpired. There are no words that can ease the pain. Yet beyond the understandable sorrow of the present, there is a need to plunge more deeply. It is important for us to reflect carefully upon the meaning of those events and how they impact our lives and service today and for the future.

We must not forget the lessons of the past and re-dedicate ourselves to the central and uncompromised mission that each of us is given to care for and defend those who cannot defend themselves and who come to us for healing. In all of its diverse facets, Navy Medicine continues its longstanding tradition of care so that we prevent the worst by promoting the best. This is what makes our service central to the mission of the United States Navy itself, namely to be a Global Force for Good.

In the light of these reflections, this edition of the *Journal of Healthcare, Science and the Humanities* rightly presents in diverse ways the broad and expansive gifts and challenges that are central to the service of those who suffer from visible and invisible wounds and frailties. As we are aware from the time of its first published edition, the *Journal* convenes through its readership a thoughtful forum of international scholars and professionals who seek to discover in each age the meaning of the central principles of healthcare: respect for

the human person; never to harm; ever to promote the good; and the provision of wellness for others each according to their needs. In this special year of remembrance, these principles are central in our re-dedication to serve the needs of others ever before serving our own. I know we all share this deeply.

Over the years of my life, I have come to know well the treasure that is human friendship, the delight that is human success, the tragedy that is human loss, and the stretching of self that is human challenge. In a certain respect, I am reminded of all this in a very meaningful way in this year and in this edition of the *Journal*. It is my sincere hope that in this special time and by reading this special edition, we all might come to appreciate a paraphrase of the Navy Medicine motto that touches each of us in our service of others all around the globe:

"Dedicated to the Human Good—Anywhere, Anytime."

Biography
Vice Admiral Matthew L. Nathan

Vice Admiral Nathan is the 37th Surgeon General of the Navy and Chief of the Navy's Bureau of Medicine and Surgery.

Dr. Nathan received his Bachelors of Science from Georgia Tech and his M.D. from The Medical College of Georgia in 1981. He completed Internal Medicine specialty training in 1984 at the University of South Florida before serving as the Internal Medicine Dept Head at Naval Hospital Guantanamo Bay, Cuba. In 1985 Dr. Nathan transferred to Naval Hospital, Groton, CT as leader of the Medical Mobilization Amphibious Surgical Support Team. In 1987, Dr. Nathan transferred to Naval Medical Center San Diego as Head, Division of Internal Medicine with additional duty to the Marine Corps, 1st Marine Division.

In 1990 he served as a Department Head, Naval Hospital Beaufort, SC before reporting to Naval Clinics Command, London, U.K. where he participated in military-to-military engagements with post-Soviet Eastern European countries. In 1995, he was assigned as specialist assignment officer at the Bureau of Naval Personnel, providing guidance to over 1,500 U.S. Navy Medical Corps officers. In 1998 he accepted a seat at the Joint Industrial College of the Armed Forces located in Washington, D.C., graduating in 1999 with a Masters in "Resourcing the National Strategy." Dr. Nathan went on to serve as the Fleet Surgeon, Forward Deployed Naval Forces, Commander, U.S. 7th Fleet, aboard the flagship USS *Blue Ridge* (LCC 19), out of Yokosuka, Japan. In 2001, he transferred as Deputy Commander, Navy Medical Center Portsmouth, VA.

In 2004 Dr. Nathan assumed command of Naval Hospital Pensacola with additional oversight of 12 clinics in 4 states where he oversaw Navy medical relief efforts following hurricanes Ivan, Dennis, and Katrina. Despite all facilities receiving crippling blows, his command still garnered the TRICARE/DOD award for "highest patient satisfaction in a medium sized facility." In June 2006, he transferred as the Fleet Surgeon to

the commander, U.S. Fleet Forces Command, instrumental in organizing the Fleet Health Domain integration with the Fleet Readiness Enterprise while providing medical global force management. In 2007, Dr. Nathan was assigned as Commander, Naval Medical Center Portsmouth and Navy Medicine Region East with command of over 18,000 personnel and an operating budget exceeding $1.2 billion.

Dr. Nathan also served as Commander, Walter Reed National Military Medical Center and Navy Medicine, National Capital Area where he was the Navy component commander to the largest military medical integration and construction project in Department of Defense history.

Dr. Nathan is board certified and holds Fellow status in the American College of Physicians and the American College of Healthcare Executives. He also holds an appointment as Clinical Professor of Medicine at the Uniformed Services University of the Health Sciences. He is a recipient of the American Hospital Association "Excellence in Leadership" award for the Federal Sector.

Dr. Nathan's personal awards include the Distinguished Service Medal (1); Legion of Merit (5); Meritorious Service Medal (2); Navy Commendation Medal, and Navy Achievement Medal (2).


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PRELUDE

Transformation: Reflections on a Living Legacy

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General Introduction

For this anniversary edition, Dr. Rueben Warren, Director of the Bioethics Center at Tuskegee University and member of the Tuskegee Legacy Committee, has authored a special Prelude. As the city of Tuskegee was the site of unethical experimentation that began 80 years ago, the University there today is the site of a renewed commitment to ethics and moral integrity in healthcare and research of all types, including public health. While citing a number of historical facts about the original study, Dr. Warren articulates in his personal reflections the importance of the Bioethics Center and its mission for national and international consciousness and a continual commitment to human respect and care. This provides a fascinating metaphor for the first pages of this edition. Due to the unethical studies from 1932–1972, the area around Tuskegee suffered as a place of tragedy. Today it is the center from which a new call for human dignity is sounded. Indeed, this typifies how a living legacy generates the power of transformative change for the betterment of humanity. Dr. Warren's reflections demonstrate that we can prevent the worst by promoting the best. His reflections underscore the ancient paradox that from the experience of curse can arise goodness.

Reflections: Yesterday, Today, and Tomorrow

Make the crooked straight
Make the straight to flow
Gather water, fire, and light.
Bring the world to a single point.

Deng Ming-Dao, 365 Tao

The ancient Chinese philosophy of Tao suggests that self-cultivation is the means for individuals to sharpen their sensibilities "to observe the workings of the great." The ethical violations by the federal government resulting from the U.S. Public Health Service Syphilis Study at Tuskegee are well known. However, the Syphilis Study was not broadly acknowledged until 1997, when then-President Clinton said, "The United States government did something that was wrong—deeply, profoundly, morally wrong." The facts vary by storyteller, but what is known is that the Syphilis Study subject population consisted of 399 syphilitic Negro [Black] males who never received treatment, 201 nonsyphilitic Negro [Black] males, with 275 of the syphilitic Negro [Black] males having been given some level of treatment during the first two years of the syphilitic process. What is also known is that,

despite the requirement for written protocols in all legitimate scientific investigations, there were never protocols written for the Syphilis Study. Several scientific papers published in the middle 1930s, by the study scientists reported the adverse effects in the syphilitic vs. non-syphilitic men. Among those with syphilis, cardiovascular diseases were fivefold higher in the men between 25 to 39 years, and twice as high among those men 40 years and older; diseases of the central nervous system were 10 times higher among those with syphilis compared to those who were nonsyphilitic. In one of the publications, the authors suggested that a 20-year observation period was needed to understand fully the disease process. Those men who were partially treated, despite all efforts by the health care community to deny care, had equally alarming results.

The President's apology, on behalf of the Nation, was for one of the most egregious ethical abuses in human subject research and healthcare in U.S. history. In addition to the Presidential Apology, by Executive Order President Clinton directed the Department of Health and Human Services to award a planning grant, ". . . so the school [Tuskegee University] can pursue establishing a center for bioethics in research and health care." President Clinton also said, "The center will serve as a museum of study and support efforts to address its legacy and strengthen bioethics training." The Bioethics Center opened in 1999.

During the previous decade, the Bioethics Center focused on educating the general public about the Syphilis Study and the critical issues related to bioethics in research and healthcare targeting African American and other underserved populations. However, in recent years, the field of bioethics has broadened to include public health ethics that focuses on ". . . the interest and health of groups, the social justice of the distributions of social resources, and the positive or social/human rights of individuals." A rigorous review of the methodology used in the original Syphilis Study suggests that the study was an epidemiological rather than a biomedical investigation. The sample population was selected based on demographic variables: African American males, undereducated, low-income and living in the rural south (purportedly with syphilis). In the light of this historical reality, over the last two years the Bioethics Center has been expanding its work to continue additional efforts in bioethics in research and healthcare, but also has included research, education and service related to public health ethics and health.

The vision of the Bioethics Center is "Shaping the Future by Promoting Optimal Health: The Future is NOW!" The mission is to enhance social justice and the Optimal Health of African Americans and other health disparity populations through research, education and service in bioethics, public health ethics, health disparities and health equity. During the 1920s–1930s, logical positivism taught that ethics defied logic and reason, were not true or false, and were fundamentally expressions of feelings. However, since the 1960s and 1970s, as a result of greater knowledge of the history of abuses in medical experimentation on human subjects (i.e., Nuremberg trials among Nazi doctors and the United States Public Health Service Syphilis Study at Tuskegee), bioethics has become more applied and pragmatic. Over the last 12 years, another sphere of ethics has evolved, called public health ethics, that, in fact, best characterizes the U.S. Public Health Service Syphilis Study at Tuskegee. Therefore, the current expansion of bioethics at Tuskegee University includes the sphere of public health ethics. Today we know that there are continued revelations about previous bioethical abuses (i.e., the 1946–48 Guatemala Syphilis Study)

in human subject research and healthcare. Nonetheless, there are efforts to transform these adverse events into lessons *learned* for researchers, healthcare providers, public health professionals and the general public by affirming and enacting measurable policies and programs to protect ethically and assure the health and well being of vulnerable and susceptible groups, as well as the general public.

All human beings are vulnerable—however, as Onora O'Neill writes in a book entitled, *Towards Justice and Virtue: A Constructive Account of Practical Reasoning*, "… some human beings may become deeply, variably and selectively vulnerable in specific circumstances, a state of destitution that needs to be addressed with sensitivity to and rejection of harm the individuals are prone to." These people or groups require care and assistance that goes beyond what others need. In his response in "The Venerable and Susceptible," published in the *Journal of Bioethics*, Michael Kottow calls this circumstance "a state of susceptibility." Any cursory review of the epidemiological literature clearly documents the demographic characteristics of the most susceptible population to health and healthcare disparities can be chronicled by race/ethnicity, class and sex; it is African American, undereducated, low-income men. This group has the same demographics as the subjects involved in the U.S. Public Health Service Syphilis Study at Tuskegee. To best address this challenge, there must be guiding ethical principles that direct human subject research, healthcare and public health. These principles must be included in education and training, and in the assessment, review, surveillance and evaluation of protocols. Only then can personal and community autonomy, benevolence, and individual and social justice be assured.

Thomas Moore, in his book, *Care of the Soul* writes, "Care of the soul is a continuous process that concerns itself not so much with 'fixing' a central flaw as with attending to the small details of everyday life, as well as to major decisions and changes." Moore describes the soul not as a thing, but as a quality or a dimension of experiencing life and the self. The dimensions of soul are applicable at the individual, group, and community level. They apply in physical, social, psychological and spiritual domains. Physically, one must be concerned with eating the right food (nutrition and diet), taking care of the body through appropriate exercise, and rest. By developing and nurturing cultural proficiencies, social "soul–caring" focuses on engaging the global community as a world citizen. Psychologically, self-cultivation and self-respect are essential assurances. Lastly, regarding the demands of spiritual soul caring, as Steven Covey wrote in his book, *Seven Principles of Highly Effective People*, spiritual well-being requires that one finds meaning and leaves a legacy.

This is the 15th year since the Presidential Apology. The focus of the Bioethics Center at Tuskegee University, and hopefully that of other persons and institutions committed to social justice, is affirming individual and community well-being by assuring bioethics and public health ethics and promoting optimal health. The spheres of ethics are evolving. Bioethics targets biomedical ethics and healthcare ethics. The latter is developing into a specific set of principles and practices that go beyond medical ethics by evaluating the merits, risks, and social concerns of activities in the field of medicine to include the duty to protect life and health, respect autonomy, act on behalf of or for the good of the patient, do no harm, and act in the best interest of others medically, even when what is healthy and in their best interest is not what they desire. The public health ethics challenges are to promote and protect life and health, balance the tension between individual autonomy

and perceptions of paternalism by public officials, intentionally "do good" on behalf of population health, and assure social justice for all regardless of power hierarchies, prestige and/or privilege.

The vision of the Tuskegee National Center for Bioethics in Research and Health Care embraces the concept of Optimal Health. In his book, *Pyramids of Power*, John Chissell, MD describes Optimal Health as a journey, not a destination, for the individual to "reach their greatest state of aliveness to move towards our greatest potential and highest good." As the opening quotation suggests, "Bring the world to a single point!" That single point related to health and healthcare must consider public health ethics as an essential element if the health of the public is to be secured.

Author Biography

Dr. Rueben C. Warren is a Professor and Director of Bioethics at the Tuskegee University National Center for Bioethics in Research and Health Care. Throughout his long and extensive professional career, Dr. Warren has maintained his involvement in continuing health professions education and in his particular roles that include planner, presenter, peer reviewer, administrator, and others. He is the author of over 100 publications that reflect his myriad presentations as a guest speaker, lecturer, and moderator. Dr. Warren's scholarly presentations include: "Comparative Health System—Lessons for Our Future;" "Minority Health is the Health of the Nation;" and "Addressing and Resisting Violence in the United States." Dr. Warren earned his Master of Divinity degree from the Interdenominational Theological Center in ethics/theology, 2007; his Doctor of Public Health degree from Harvard School of Public Health, 1975; his Master of Public Health degree from Harvard School of Public Health, 1973; his Doctor of Dental Surgery from Meharry Medical College in dentistry, 1972; and his Bachelor of Arts degree from San Francisco State University in biology, 1968.


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ARTICLES

Eighty Years of Bad Blood: The Evolution of Human Research after the Tuskegee Study

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Author Note

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Abstract

The year 2012 marks the eightieth anniversary of the beginning of the U.S. Public Health Service's (PHS) study on the effects of untreated syphilis in Tuskegee, AL, which lasted from 1932 to 1972. The research continued after penicillin became widely available and was known to be an effective treatment for syphilis. To justify the experiments, the PHS argued that the study was a never-to-be-repeated opportunity. Did the U.S. government continue to take advantage of never-to-be-repeated opportunities in medical research by using unethical justifications? This manuscript will explore how America's growing understanding of human research and the rights of human subjects have mirrored the growth of regulatory law and jurisprudence since the Tuskegee Study. We will examine PHS human research experiments in Guatemala from 1946 to 1948, as well as the U.S. Department of Justice's decision not to prosecute members of the Japanese Army despite having received information on human experiments they conducted on World War II Prisoners of War (POWs). We recognize that numerous events have contributed to current human research practices and it would be impossible to discuss every significant topic. We submit that society's ethical considerations regarding human research have progressed over the past eighty years. In this article we concentrate on the growing protections of the right to informed consent. We contend that

constant and consistent oversight by the three branches of U.S. government is necessary to ensure human rights protection of those classes least able to protect themselves and prevent another Tuskegee Study.

Keywords: Tuskegee Study, human research, informed consent, Nuremberg Code, ethics.

Introduction

"The future of the Negro lies more in the research laboratory than in the schools…"
–Thomas Murrell, M.D., U.S. Public Health Service, 1910 (Washington, 2006, p. 157)

The year 2012 marks the eightieth anniversary of the beginning of the United States Public Health Service's (PHS) study of untreated syphilis in Tuskegee, AL. Since 1972, the word "Tuskegee" has functioned as a metaphor linking varied concerns about health care research and human experimentation (Reverby, 2010). From 1932 to 1972, the PHS conducted a study called the *Study of Syphilis in the Untreated Negro* (Tuskegee Study), which promised free medical care to desperately poor sharecroppers in Macon County, AL (Reverby, 2009). The study was designed to observe the progression of syphilis in black men (Reverby, 2009). The Tuskegee Study officially began when Dr. Taliaferro Clark, chief of PHS Venereal Disease Division, suggested that the PHS save the expense of treatment by merely observing the course of the disease in blacks and publish the data (Brandt, 1978). 439 African American men with late stages syphilis were selected as research subjects, and 185 without the disease became the study's control group (Washington, 2006).

In 1908, Congress established the Division of Venereal Diseases within PHS. Within a year, 44 states had organized separate bureaus for venereal disease control. Data collected from a 1926 survey of 25 communities across the United States indicated that the incidence of syphilis among patients under observation was "4.05 cases per 1,000 population, the rate for whites being 4 per 1,000, and that for Negroes 7.2 per 1,000" (Fourtner, Fourtner & Herreid, 2007, p. 2). It was believed that syphilis manifested differently in blacks than in whites. PHS physicians were determined to document this theory by using a pool of infected black men in Macon, AL and withholding effective treatment and charting the progression of symptoms of the disorder. Penicillin was identified as an effective cure for syphilis in 1945 and became widely used by the federal government by 1947 (Washington, 2006). The purpose of the Tuskegee Study was not to treat the disease but to observe its impact upon the body. The study continued after the subjects died. The physician-researchers performed autopsies in order to trace the ravages of the disease in their bodies in the final stage of the study (Washington, 2006). Crucial to both the study's volunteers and this note, PHS did not inform the men that they were research subjects being followed in a no treatment study (Reverby, 2009).

For the experiment to be successful, it was imperative to convince the participants of the legitimacy of the program. It is likely the presence of the Tuskegee Institute and the John Andrew Memorial Hospital at the Tuskegee Institute (now Tuskegee University) in Macon County made the site scientifically attractive (Washington, 2006). The PHS used black physicians and nurses from the John A. Andrew Memorial Hospital to convince the subjects to trust the PHS physicians and participate in the study. In 1930, Macon County

had 27,000 residents, 82 percent of whom were African-Americans, most living in poverty in shacks with dirt floors, no plumbing, and poor sanitation. A 1929 PHS syphilis survey of black Alabama residents determined a high rate of 36 percent in Macon County. PHS health officials announced they had come to test people for "bad blood," a term used for a host of maladies and few people connected the term with syphilis (Fourtner, Fourtner & Herreid, 2007). The study's target population was people who had never been treated by a doctor (Fourtner, Fourtner & Herreid, 2007). The government's offer of free healthcare was a significant enticement (Reverby, 2009). The men believed they were being treated for a vague illness. However, the researchers only provided aspirins, tonics, and diagnostic spinal taps as treatment for their bad blood. Nothing was provided to treat syphilis.

> *Note 1*. In 1910, Paul Ehrlich introduced the arsenic-based drug Salvarsan as a remedy for syphilis. Salvarsan proved to be amazingly effective, particularly when compared with the conventional therapy of mercury salts. Salvarsan fell short of being a perfect remedy for syphilis. Patients with later stages of syphilis didn't respond as well to the drug and physicians found the drug difficult to handle and administer properly. Nevertheless it remained the most effective drug for syphilis until penicillin became available in the 1940s (Yarnell, 2005).

The Tuskegee Study was not conducted in secret. The results of the experiment were widely published in medical literature over several decades and included 28 deaths, 100 cases of disability, and 19 cases of congenital syphilis (Josilin Diabetes Center Committee on Human Studies, 2010). Medical articles charting its progress appeared over the decades, even though a number of healthcare professionals questioned the study's ethics (Reverby, 2009). Since its media exposure to the general public in July 1972, the Tuskegee Study has gained nearly as much power as slavery and lynching as a metaphor for the government's refusal to consider African Americans as rights-bearing citizens (Reverby, 2010).

PHS doctors frequently defended the study and their failure to offer effective therapy by insisting that blacks with syphilis would never voluntarily seek treatment. However, this does not explain why they enticed study subjects by disguising the experiment as a treatment program (Washington, 2009). When questioned about the ethics of continuing the study after a cure for syphilis was discovered, PHS supervisors argued that it was a never-to-be-repeated opportunity. Dr. John Heller, Director of Venereal Diseases at the PHS from 1943 to 1948, stated, "the men's status did not warrant ethical debate. They were subjects, not patients; clinical material, not sick people" (Quinn & Thomas, 2000, p. 297)

Did the U.S. government continue to take advantage of situations defined as never-to-be-repeated opportunities around the world to advance medical research? This manuscript will explore America's growing understanding of human research and the rights of human subjects since the Tuskegee Study as mirrored in the growth of regulatory law and jurisprudence. Although it is not possible to discuss every event that has contributed to the government's current human research policies, we will examine several significant topics that measure the progression from the Tuskegee Study to today.

This manuscript will examine PHS' human research experiments in Guatemala from 1946 to 1948, the U.S. Department of Justice's decision to not prosecute members of the Japanese Imperial Army for war crimes in exchange for information collected

from experiments they conducted on World War II Prisoners of War (POW) and civilian noncombatants, as they both overlap the years of the Tuskegee Study. We will then discuss both international and domestic statutory law. We submit that society's ethical considerations regarding human research have progressed over the past eighty years. However, constant and consistent oversight by the three branches of U.S. government is necessary to maintain the preservation of human rights and prevent another Tuskegee Study.

Bringing a Dark Chapter to Light: PHS' Human Research Experimentation in Guatemala from 1946–1948

"John Hopkins School of Hygiene and the University of North Carolina have discovered that small doses of penicillin,…prevents syphilis from developing. The case holds good for rabbits but no tests on human beings have yet been made. Since this is ethically impossible, it may take years to gather the information needed." *The New York Times*, April 27, 1947 (*Bioethics Commission Report*, 2011, p. 10)

Policy is often made based on historical understanding of particular events. The PHS involvement in the Tuskegee Study arguably shaped U.S. policy surrounding human subject medical research more than any other medical experiment (Reverby, 2011). However, it could be argued that the government's involvement in the Tuskegee Study was mild compared to the human subject research that was concurrently conducted just beyond American borders in Guatemala. The Tuskegee research could be considered conservative when compared to the government's involvement in another, much more invasive, human research project in Guatemala from 1946–1948 (hereafter known as the "Guatemala Experiment").

> *Note 2.* On October 1, 2010, President Barack Obama telephoned President Àlvaro Colom of Guatemala to extend an apology to the people of Guatemala for medical research supported by the U.S. and conducted between 1946 and 1948. President Obama expressed deep regret for the research and affirmed the U.S. government's unwavering commitment to ensure that all human medical studies conducted today meet exacting standards for the protection of human subjects. Secretary of State Hillary Rodham Clinton and Secretary of the Department of Health and Human Services (HHS) Kathleen Sebelius also offered a formal apology to Guatemala for this research, which they called abhorrent, unethical, and reprehensible. The apology statement was published in English and Spanish (U.S. Department of Health and Human Services, 2010; Tanne, 2010; Bioethics Commission Report, 2011).

Although conducted over sixty-three years ago, the PHS' involvement in Sexually Transmitted Disease (STD) human research in Guatemala only recently came to light. These experiments may have remained lost to history were it not for the efforts of Wellesley College Professor for Women's Studies, Susan M. Reverby, PhD who unearthed the notes of Dr. John C. Cutler, a PHS physician who later spent time as a member of the team carrying out the Tuskegee Study (Gorski, 2010). Dr. Reverby unveiled the Guatemala Experiment and our government's involvement in her article "'Normal Exposure' and Inoculation Syphilis: A PHS "Tuskegee" Doctor in Guatemala, 1946–1948," which was published in the *Journal of Policy History* in January 2011 (Reverby, 2011).

Dr. Reverby recognized that her publication would cause international indignation and could severely damage U.S. international relations. She provided a copy of her article, pre-publication, in late June 2010 to Dr. David Sencer, the former director of the Centers for Disease Control and Prevention (CDC), who informed others in the CDC about Dr. Reverby's article and its implications. The CDC dispatched Dr. John Douglas, a leading syphilis expert, who examined the records and provided a report that confirmed Dr. Reverby's findings. The unpublished article and Dr. Douglas's report made it up the chain of command through the CDC to HHS, the Department of State, and the White House (Reverby, 2011).

After reading Dr. Reverby's report, President Barack Obama charged the Commission for the Study of Bioethical Issues to oversee a thorough fact-finding investigation into the specifics of the Guatemala Experiment. The President also charged the Commission to investigate current human subject protection measures to determine if federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the federal government (*Bioethics Committee Report*, 2011).

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES

President Barack Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President:

On behalf of the Presidential Commission for the Study of Bioethical Issues, we present to you this report, *"Ethically Impossible": STD Research in Guatemala from 1946 to 1948*. In response to your request of November 24, 2010, the Commission oversaw a thorough fact-finding investigation into the specifics of the U.S. Public Health Service-led studies in Guatemala involving the intentional exposure and infection of vulnerable populations.

Following a nine-month intensive investigation, the Commission has concluded that the Guatemala experiments involved gross violations of ethics as judged against both the standards of today and the researchers' own understanding of applicable contemporaneous practices. It is the Commission's firm belief that many of the actions undertaken in Guatemala were especially egregious moral wrongs because many of the individuals involved held positions of public institutional responsibility.

The best thing we can do as a country when faced with a dark chapter is to bring it to light. The Commission has worked hard to provide an unvarnished ethical analysis to both honor the victims and make sure events such as these never happen again.

The Commission is also working to fulfill your other charge on human subjects research—a review of domestic and international contemporary human subjects protection rules and standards, to ensure federally funded scientific studies are conducted ethically—and will submit a report to you in December.

The Commission is honored by the trust you have placed in us and grateful for the opportunity to serve you and the nation in this way.

Sincerely,

Amy Gutmann, Ph.D.
Chair

James Wagner, Ph.D.
Vice-Chair

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In 2011, the Presidential Commission for the Study to Bioethical Issues ("Bioethics Commission") investigated Dr. Reverby's findings. Their report confirmed that a significant amount of American tax dollars contributed to the deliberate infection of nearly 1,308 Guatemalan citizens with various venereal diseases without their informed consent. Of the 1,308 subjects exposed to STDs, the research documented some form of treatment for 678 subjects. Additionally, the researchers conducted diagnostic testing of 5,128

subjects including soldiers, prisoners, psychiatric patients, children, and leprosy patients. The diagnostic testing, which included blood draws and spinal taps continued through 1953 (McNeil Jr., *Bioethics Commission Report*, 2011). The results of the Commission's investigation were released in September 2011.

U.S. Government's Review and Approval of the Guatemala Experiment

Like the Tuskegee Study, the Guatemala Experiment was not the result of a closed-door discussion in an obscure government office. The *Bioethics Commission Report* explains the process used to review and fund the program. President Franklin D. Roosevelt's newly established Office of Scientific Research and Development (OSRD) and its Committee on Medical Research (CMR) provided STD researchers an unprecedented opportunity to mobilize federal funds to mitigate the threat of STDs. Housed at National Institute of Health (NIH), a new system for federally funded biomedical research emerged where OSRD contracts were converted into PHS grants. PHS leadership established a dual review structure for evaluating funding applications (*Bioethics Commission Report*, 2011).

Study sections, composed of independent, usually civilian, peer scientists and representatives from the Army, Navy, Veterans Administration, and PHS, made recommendations about the applications' scientific merit and an advisory council considered policy implications in addition to evaluating questions of scientific merit. The Surgeon General made final funding decisions. This new system became operational in early 1946 and reviewed the proposal for the Guatemala Experiment as one of 30 projects considered at its first meeting on February 7–8, 1946. The first study section established under this new structure was the Syphilis Study Section. The study section approved the proposal for "the Guatemala study dealing with the experimental transmission of syphilis to human volunteers and improved methods of prophylaxis" (*Bioethics Commission Report*, 2011, p. 31). On March 8–9, 1946, PHS Deputy Surgeon General Warren Draper presided over the National Advisory Health Counsel (NAHC) meeting that recommended funding the proposal. It was funded shortly thereafter as Research Grant no. 65 (RG-65) (*Bioethics Commission Report*, 2011).

PHS does not bear the entire burden for this ethically questionable medical study. The *Bioethics Commission Report* cited the U.S. Surgeon General, the Attorney General, U.S. Army and Navy medical officials, the president of the American Medical Association, the president of the National Academy of Sciences and experts from Harvard, John Hopkins, and the Universities of Pennsylvania and Rochester as giving advanced approval in principle for the experiments (McNeil, 2011). As subjects, the PHS chose typical targets from vulnerable populations: prisoners in a national penitentiary, patients in Guatemala's only mental hospital, children in the national orphanage, and soldiers in barracks at the capitol (Reverby, 2011).

Methods of Human Research during the Guatemalan Experiment: Use of Commercial Sex Workers for Normal Exposure

The PHS researchers went to great extremes to infect human subjects with sexually transmitted diseases. Recognizing the benefit of state regulated prostitution, researchers sought and received the cooperation of the Guatemalan Government. Every commercial sex

worker was required to register with the Guatemalan government for health screening. Those that were identified as having syphilis were directed to PHS and paid with U.S. tax dollars to have sexual intercourse with inmates in the national penitentiary (Gorski, 2010). The PHS researchers artificially inoculated numerous commercial sex workers with gonorrhea by moistening a cotton-tipped swab with pus from an acute case of gonorrheal urethritis, inserting the swab into the woman's cervix and "swabbing it around...with considerable vigor" (Reverby, 2011, *Bioethics Commission Report*, 2011, p. 46). The commercial sex workers infected in this manner reportedly contracted the disease and were sent to the prison to expose the men (Reverby, 2011; *Bioethics Commission Report*, 2011). The men were divided into groups and various chemical and biological prophylaxis techniques were tested after presumed infection. If positive, the men were then provided with enough penicillin to produce a cure (Reverby, 2011).

There is no record in any of the available documents that the women consented to being a part of the experiments or had any idea that they were infected with STDs by the researchers. Medical records reflect that at least one commercial sex worker used in these prophylaxis experiments was 16 years old (Reverby, 2011; *Bioethics Commission Report*, 2011).

Artificial Inoculation

Dr. Cutler and his team went beyond using prostitutes to test prophylaxis against STD transmission. They practiced direct inoculation using material from syphilitic growths on the testicles of infected rabbits and scrapings from the penile chancres of infected men (Gorski, 2010). During the experiments, the subject's penis was abraded by scraping the skin with a hypodermic needle, and drops of the syphilitic emulsion were placed on a small cotton pledget and through it to the roughed skin on the man's penis for at least an hour, sometimes two (Reverby, 2011). Females were exposed by applying an infected pledget after needles were used to abrade the women's forearms, face or mouth (Reverby, 2011). These methods of direct inoculation were compared with other methods of introducing the disease, including ingestion of syphilitic tissue mixed with distilled water, introduction into the spinal fluid, and direct injection into the bloodstream (Gorski, 2010).

Serology Testing in Children

The PHS physicians found it difficult to conduct a sufficiently controlled experiment on prison inmates and decided that certain parts of the studies could be better done elsewhere. Serology testing in children began sometime before June 1947 and ended in summer 1949. The researchers conducted physical examinations, blood draws and lumbar punctures (*Bioethics Commission Report*, 2011). With the cooperation of the Guatemalan government, the researchers used 1,384 children between the ages of one and eighteen from an orphanage at Port of San José, Totonicapán (Reverby, 2011; *Bioethics Commission Report*, 2011). According to Reverby (2011), none of the children were inoculated with an STD. Three children who appeared to have congenital syphilis were given penicillin. Another eighty-nine gave positive results but showed no clinical signs of the disease. The PHS physicians used blood tests from the orphans to rule out confounding factors related to syphilis treatment that they could not identify (Reverby, 2011).

STD Inoculation in the Psychiatric Hospital

After testing the inmates, PHS physicians were still unable to determine whether penicillin could be used to preserve the patient's health and prevent syphilis from spreading, as compared to other chemicals applied directly to the genitalia so they broadened the program to experiment on patients in the country's only asylum (Reverby, 2011). A total of 446 psychiatric patients were involved in intentional STD exposure, 294 of whom received some form of treatment. The patients were not informed about the inoculum they were given, which contained syphilis spirochetes (Reverby, 2011). There is no evidence that the psychiatric subjects gave consent or understood that they were involved in an experiment (*Bioethics Commission Report*, 2011).

Like the Tuskegee Study, full cooperation was sought with the institution, not with the subject–patients or their families. Dr. Carlos Salvado, the Director of the psychiatric hospital, collaborated on the experiments and made staff available to assist the PHS researchers. Dr. Cutler credited Dr. Salvado with suggesting use of the psychiatric patients "since we had available a certain and sure cure for syphilis...." (*Bioethics Commission Report*, 2011, p. 58). In exchange for Dr. Salvado's cooperation, PHS supplied needed anti-convulsant drugs because a large part of the population was epileptic. They also bought a refrigerator for biologicals, a motion picture projector for inmate recreation, and metal cups, plates and forks to supplement the inadequate supply (Reverby, 2011).

PHS' Ethical Reasoning for their Activities in Guatemala and their Justification for the Concurrent Tuskegee Study

The similarities between the Guatemala and the Tuskegee Studies are stark. Both studies arose from the Venereal Disease Research Laboratory (VDRL), which later became part of CDC; both involved some of the same researchers; and both studies concerned syphilis research. The two experiments involved deliberate efforts to deceive the subjects and the public community that might have objected to the work (Bioethics Commission, 2011). It is important to note, however, the Guatemalan Experiment differed from the Tuskegee Study in two significant ways. First, in Guatemala, physicians deliberately inoculated the subjects with syphilis, gonorrhea and chancroid; and second, penicillin treatment was administered to most of the subjects (Reverby, 2011). During the Tuskegee Study, government physicians did not inoculate the subjects with syphilis and the subjects were never provided penicillin treatment. Furthermore, the ethical justification for both studies is highly questionable. While the Guatemalan Experiment proceeded *because* the penicillin cure was readily available to treat the infections, the Tuskegee Study proceeded without providing treatment *despite* the wide availability of treatment. This suggests that American researches were willing to adjust their justification for questionable studies.

Ethical Justification for the Study

The physicians who conducted the Guatemala Experiment seemed to have adopted the attitude that violating ethical principles is sometimes necessary to advance medical science. It is evident that many of the officials who knew of or participated in the experiment knew it was unethical. In April 1947, before any intentional syphilis exposure experiments began at the psychiatric hospital, a PHS supervisor wrote to Dr. Cutler that he was "a bit, in fact

more than a bit, leery of the experiment with the insane people" as they cannot give consent and do not know what is going on (Reverby, 2011, p. 18). The physician was primarily concerned about exposure to criticism, because if "some goody organization got wind of the work, they would raise a lot of smoke" (*Bioethics Commission Report*, 2011, Reverby, 2011, p. 18). Reverby's (2011) article exposing the Guatemala Experiment described Dr. Cutler's justification for his methods. He reminded his supervisors that "normal sex leads to this kind of trauma and minute lacerations" (Reverby, 2011, p. 17). This PHS supervisor's anxiety was similar to Dr. Cutler's concerns during the Tuskegee Study. Gorski's (2010) article in *Science-Based Medicine* states that Dr. Cutler was reported to have said,

> "As you can imagine, we are holding our breath, and we are explaining to the patients and others concerned with but a few key exceptions, that the treatment is a new one utilizing serum followed by penicillin. This double talk keeps me hopping at times" (Gorski, 2010).

The physicians in Tuskegee did not inoculate the men in Macon, Alabama with syphilis. They merely observed the progression of the disease. Moreover, they provided critical healthcare to people who could not afford health care treatment. It appears they believed their actions did not cross moral boundaries since they were observing individuals who had already contracted syphilis and were not infecting them with disease. The subjects were not harmed directly by the PHS study. However, these physicians should have contemplated the fact that the African American Tuskegee subjects were not offered the penicillin cure that was given to the Guatemalan citizens.

Government Collusion

It is important to note that the PHS conducted the Guatemalan Experiment with assistance from the Guatemalan Ministry of Justice and the warden of Guatemala City's Central Penitentiary (Reverby, 2011). This consent verifies that there was traffic in ideas, in practices, in justifications, and in the bodies of researchers that moved across borders (Anderson, 2009). The Guatemalan government shared the same scientific curiosity as the American researchers and was willing to enter into a partnership that exchanged American financial resources for Guatemalan test subjects. This same quest for information exchange and trading money or favors for research was also reflected in a more individually brutal example in Asia during World War II. While the U.S. government did not participate directly in those experiments, they sought to profit from the extremely unethical medical research of their declared enemies by trading on what it could control: post-war tribunals and prosecution.

Complicity after the Fact: U.S. Profit from Medical Experimentation by the Japanese in WWII

The overtly unethical and direct actions of American researchers in Guatemala can be compared with the role of the U.S. government in helping Japanese military researchers evade prosecution for war crimes for their medical experimentation on prisoners of war (POWs) and civilians in pursuit of research to advance biological warfare (BW) programs during World War II. These experiments were violent and cruel in the extreme and often led to the death of the subject (Galvin, 2003; Kaufman, 2008; Harris, n.d.). Responsible

for organizing both the Nuremburg Trials and the parallel International Military Tribunal for the Far East, commonly known as the Tokyo Trials, the U.S. government is believed by many to have brokered a deal with Japanese officials to decline prosecution for what were even then considered war crimes in exchange for access to the medical research gathered from the human experiments. It is difficult to argue that POWs are not a vulnerable class with virtually no ability to freely consent to medical experimentation. No U.S. agents took part in the actual forced medical experiments, however moral and ethical ramifications of not only failing to prosecute but presumably gaining strategic advantages from clearly illegal and immoral human medical experimentation are still open. Nearly identical behavior from the Germans was not only vehemently denounced, but an entire body of law, the Nuremberg Code, grew from the prosecution of that behavior. One questions why their allies in the Far East were treated so differently.

Japanese Human Medical Experimentation Unveiled

Japanese officials ran large medical experiments using thousands of Allied service members, possibly including U.S. POWs, and local civilians as unwilling human test subjects at several locations throughout China and Singapore from the 1930's through Japan's surrender (Nie, 2006; Kaufman, 2008; Bradsher, Drea, Hanyok, Lide, Paterson, & Yang, 2006; Harris, n.d.). The most notorious of these experimentation centers, Unit 731, was run by the Imperial Japanese Army and located in the Manchurian town of Harbin (Galvin, 2003). Experiments on human subjects included anthrax exposure, extreme cold exposure to induce frostbite, testing plague–infested flea bombs, extended tourniquet application for periods up to seven or eight hours, vivisection of lungs, hearts, livers and stomachs, dissection, weapons testing, starvation, dehydration, injection of subjects with bubonic plague, cholera, anthrax, smallpox and syphilis, and the use of victims to demonstrate surgical techniques (Galvin, 2003; Kaufman, 2008; Harris, n.d.). Subjects often did not survive or were killed once the experiments were over. The Japanese military also exposed masses of local civilians to biological agents to test their responses. It is estimated that the death toll from Unit 731's experimentation efforts range from 80,000 to 200,000, including about 10,000 Chinese from the surrounding area that were massacred en masse just prior to Japan's surrender (Galvin, 2003).

This extreme medical testing was intended to aid the development of advanced biological warfare weapons for use against Allied forces in the Pacific (Kleinman, A., Guo, N., Nie, J. B., & Selden, M., 2010). Clearly, the POWs and civilian noncombatants were unable to give any meaningful consent to such medical experiments. The research data gathered from such a large and aggressive operation was presumably extensive but unquestionably ethically tainted in its production. The way the United States chose to balance those competing interests is chilling.

The U.S. Deal with Japan: Blood Money

After World War II concluded, the U.S. government offered extremely profitable incentives, including immunity for war crimes and money, to thousands of Japanese researchers, medical professionals and military members in exchange for the results of their human medical experimentation efforts, including the atrocities inflicted by Unit 731 (Kaufman, 2008; Nie, 2006). Although there is some evidence that initial reports concluded

no human experimentation had occurred, by 1947 it would have been impossible to deny knowledge that these widespread programs had been in place (Nie, 2006).

It can hardly be overlooked that at the very same time the U.S. government was pursuing prosecution of Nazi medical experimenters, similar actions were not prosecuted in the parallel Tokyo Trials (Nie, 2006). The Supreme Commander for the Allied Powers, General MacArthur, was responsible for organizing the tribunals to hear allegations of war crimes. Although it has been claimed that he lacked definitive evidence to prosecute this group at the War Crimes Tribunal, time would expose that repeated promises were made not to prosecute those perpetrators in order to obtain their medical data for use by the U.S. military, presumably as a matter of national security (Bradsher et al, 2006; Nie, 2006; Kaufman, 2008). More overtly, the U.S. is alleged to have withdrawn critical information from consideration at the Tokyo Trials (Nie, 2006). Clearly German and Japanese perpetrators were treated quite differently for nearly identical offenses. Balancing the risk of embarrassment sometime in the future and untold medical research gain at the time, government officials took the risk in exchange for what was hoped to be extremely valuable information (Nie, 2006). It is unclear exactly what useful information the U.S. received for its bargain.

Ethical Discourse

Unlike other direct action offenses by the medical community cited in this note, the central issue is not the ethical treatment of the victims of forced medical experimentation but the State's cover up of those atrocities in exchange for medical and research information deemed of vital interest to national security. For the sake of argument, we will assume the information secured from this pact was, in fact, of strategic importance, even that it helped in a tangible and demonstrative way to help secure national interests, particularly before the international agreement was ratified banning the use of biological agents as an offensive weapon. Getting to the "right" answer is not enough when the means and method of the arrival is fraught with disastrous ethical analysis.

The effects of human medical experimentation on POWs and detained persons in the West and the Allied response through the Nuremburg Trials are widely expounded upon in other forums. The most succinct and rational explanation for the disparity of treatment of the Japanese perpetrators of equally if not more offensive practices is that we reasoned, as a country, we could get away with it and the opportunity to profit from this experimentation was too good to pass up. If it was outrageous in the West, why was it not equally outrageous in the East?

> The questions of ethics and morality as they affected scientists in Japan and in the United States never once entered into a single discussion that is recorded in any of the minutes, notes, records of meetings, and so on, from the initial Murray Sanders reports of November 1945 to the Joint Chiefs of Staff cable to General MacArthur on March 12, 1948. In all the considerable documentation that has survived over the more than five decades since the events described, not one individual is chronicled as having said BW human experiments were an abomination and that their perpetrators should be prosecuted
>
> (Nie, 2006; Harris, n.d.).

A repeating pattern emerges showing that those in a position least able to advocate for themselves are treated differently and worse. Although many combatant POWs were also victims of these practices, including some U.S. servicemen, the vast majority of victims were from occupied Asian countries, primarily China. That fact should not be discounted in theorizing on the basis of such disparate treatment of the perpetrators of the crimes.

> The U.S. cover–up of Japanese medical atrocities for … nearly fifty years constitutes a typical case of racism in American officials, scientific and medical professionals, and society in general in dealing with international relations, just as the notorious Tuskegee syphilis study undertaken by the U.S. Public Health Service…represents the archetype of American racism in domestic affairs.
>
> (Nie, 2006)

Why should our community care about this cover-up? After all, U.S. officials were not themselves the direct perpetrators of the medical experiments, nor did the information collected disappear, whether its creation was voluntary or not. For the sake of argument, we will assume the research was actually usable as intended. We should consider whether profiting from another's abhorrent, unethical and reprehensible conduct does not make us complicit and blameworthy due to our failure to pursue justice for those we were sworn to liberate and protect. To procure the results from the Tuskegee and Guatemala Experiments as well as the Japanese biological warfare experiments, the notion that great progress required sacrifice superseded ethical hesitation about violating the rights of the test subjects.

Comparing the Experiments and Exchange to Today's Human Research Regulations

Both the Tuskegee Study and the Tokyo Trials exchange were ethically reprehensible, but the U.S. government took a comparatively passive approach to violating the rights of test subjects. In the one, observing the status quo while obfuscating the truth about treatment provided, in the other profiting from the unethical actions of others. The Guatemala Experiment was much more directly invasive and unquestionably unethical both from medical and legal standards. The Bioethics Commission concluded that the Guatemala Experiment was a gross violation of ethics, not just by today's standards but by those of the time as well (McNeil, 2011).

Today's standards of ethical human subject research are controlled by medical ethics literature and federal regulations, which include the National Research Act (1974), the U.S. Food and Drug Administration (FDA) Drug Amendments of 1962, and the Declaration of Helsinki (1964). These laws share numerous human research principles including informed consent, an essential principle ignored in all experiments herein discussed. They also include the principles of autonomy and dignity; the requirements for minimization of risks; a reasonable balance of risks and benefits; sound scientific justification; protection of privacy and confidentiality; and special protections for those who are especially vulnerable, including minors, prisoners, and those with impaired decision making. Equally important is the requirement for a careful and accountable independent review prior to the initiation of clinical research (*Bioethics Commission Report*, 2011).

As the Commission's investigation shows, there is no evidence that consent was sought or obtained from the subjects of the Guatemala Experiment. There was no independent review of the study before its implementation. With no review, the experiments were haphazardly designed and initiated with little apparent appreciation for the risks and benefits to the subjects. Additionally, the experiments included populations that are currently recognized as vulnerable and thereby should receive added safeguards to ensure protection under today's standards (*Bioethics Commission Report*, 2011).

The Establishment of the Nuremberg Code and an International Standard for Ethical Human Research

On December 9, 1946, an international military tribunal opened criminal proceedings against 23 leading Nazi physicians for their willing participation in war crimes and crimes against humanity. Nazi physicians and scientists had carried out extensive human experimentation and murders during the Second World War (Grodin, 1994). These hearings, known as the Nuremberg Trials, represented a critical intervention in the history of prosecutions. For the first time in history, an international military tribunal was challenged by the world to create and apply a prosecutorial legal standard for mass violence and crimes against humanity (Nuremberg Trial Fact Sheet, 2011).

The tribunal was confronted with the question of how to determine the appropriate standards of care for human experimentation. The court sought an historical framework of medical standards from which to judge the Nazi physicians. In doing so, they established a code of human experimentation principles that would serve as a policy for research ethics, known as the Nuremberg Code. The 1948 Nuremberg Code was not the first code of human experimentation, nor was it the most comprehensive. Perhaps it was the unprecedented nature of the atrocities committed by Nazi physicians that has made the Nuremberg Code the hallmark for all subsequent dialogs on the ethics of human experimentation (Grodin, 1994). The Nuremberg Code established ten points defining legitimate medical research and included such novel principles as informed consent, absence of coercion, properly formulated scientific experimentation, and beneficence towards experiment participants. The ten points of the Nuremberg Code are as follows:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent and should be able to exercise free power of choice, without any element of force, fraud, deceit, duress, or other form of coercion; and should have sufficient understanding of the study as to enable him to make an enlightened decision. Informed consent requires that the subject know the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon everyone who initiates, directs or engages in the experiment. It is a personal duty and responsibility, which may not be delegated to another.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease so that the anticipated results will justify the performance of the experiment.

4. The experiment should avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against the possibility of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. The human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to end the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject (U.S. Government Printing Office, 1949).

Although it did not carry the force of law, the Nuremberg Code was the first international document that advocated voluntary participation and informed consent (Office of Research Integrity–Human Subjects Research UNLV, 2011).

Ironically, while the Nuremburg Code was being developed in Europe, PHS physicians were advocating for the continuation, and expansion of the Tuskegee Study, which clearly violated the first, fourth and fifth points of the Code. Although the Nuremberg court was an international tribunal, an American-led bench created the Code. America's involvement in the creation of the Nuremberg Code demonstrated its global commitment to ethical human research and the protection of human rights. However, since the U.S. Legislature did not codify the Nuremberg Code, PHS physicians were permitted to continue their studies in Tuskegee and Guatemala without penalty of law.

From 1948 until the public exposure of the Tuskegee Study in1972 the U.S. enjoyed twenty-four years of perceived moral superiority. They defeated Nazi Germany in the West and ended the expansion of the Japanese Empire in the East. The U.S. publicly awarded swift punishment to those who committed odious offenses that constituted an attack on human dignity, their deal with members of the Japanese Imperial Army notwithstanding. Perhaps this era of good feelings allowed the U.S. to mask the actions of their physicians and convince themselves that the Tuskegee Study and the Guatemala Experiment were conducted for the benefit of the greater good. It is not difficult to imagine a post-WWII America which felt a sense of responsibility for people around world.

Application of the Informed Consent Principle through Global Policies and Federal Regulations

Since its development, many physicians have avoided using the Nuremberg Code as the ethical and procedural standard for their human research experiments because they wanted to distance themselves from any link to the Nazi atrocities that the Code was meant to prevent. Noting that the Code applied primarily to the type of outrageous nontherapeutic experiments conducted during the war, physician groups tended to find the Code too legalistic and irrelevant to their therapeutic experiments, which were often viewed as treatment methods instead of experiments. They refused to be bound by the specific requirements of the Nuremberg Code and sought an alternative code to guide medical researchers (Annes, 1991).

The most successful and influential guidance for post-Nuremberg Code human research has been the World Medical Association's (WMA) Declaration of Helsinki, adopted in 1964. The declaration has been amended three times since its adoption. The WMA was formed at the headquarters of the British Medical Association in London. The hope was that should war ever come again, the WMA would act as the authoritative body governing the adjudication of medical war crimes. Hugh Clegg, editor of the *British Medical Journal*, was given the task of drafting the Declaration of Helsinki. In a 1960 article, Clegg reviewed the Nuremberg Code with general approval but concluded that, so long as the research worker is imbued with the Hippocratic ideal, this and his conscience should be sufficient guide (Annas, 1991). By the early 1970's the Declaration of Helsinki was widely admired by physicians as an advance over the Nuremberg Code because, in their opinion, it was an ethical, as opposed to a legalistic, document and was more useful than what was formulated at Nuremberg (Annas, 1991).

Although the Declaration of Helsinki is not a legally binding instrument in American law, it draws authority from the degree to which it has been adhered to in the practice of human experimentation. In 1964, seventeen years after the establishment of the Nuremberg Code (and in the midst of the Tuskegee Study), research physicians were still convinced that individual practitioners could be trusted to formulate appropriate ethical standards for human research experiments. History has shown, as evidenced by the Japanese WWII human experiments at Unit 731 and PHS' prolonged association with the Tuskegee Study, that physicians should not be given blind authority to determine the ethical boundaries of their human research studies.

Enactment of the 1974 National Research Act

"It is always with the best intentions that the worst work is done." (Wilde, 1907, p. 197)

On July 12, 1974, the National Research Act was enacted in response to the full exposure of the government's involvement in the Tuskegee Study. This act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the National Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines to assure that such research is conducted in accordance with those principles (Office of Research Integrity UNLV, 2011). The National Commission developed the expression "basic ethical principles," which refers to those general judgments that serve as a basic justification for the ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our culture, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice (Braunschweiger, 2000).

In 1978, the National Commission published Ethical Principles and Guidelines for the Protection of Human Subjects of Research, also known as the Belmont Report, named after the Belmont Conference Center where the Commission met when drafting the report. The Belmont Report also identifies the three fundamental ethical principles for human subjects research that was established by the National Commission in 1974 (Office of Research Integrity UNLV, 2011).

The Belmont Report and the National Research Act suggest that today's medical practitioners are taught that autonomy, beneficence and justice are the ethical principles that should govern research that involves human subjects. The federal government controls the ethical practices of most human research projects by withholding funding unless specific conditions are met. The cornerstone of ethical human research study is informed consent, which was established in 1947 by the Nuremberg Code.

Since the Macon County men voluntarily participated in the Tuskegee Study, the PHS physicians may have argued that they conducted the Tuskegee Study with consent of their subjects. The men were told they had an illness and they chose to accept the government's free medical care. Therefore, the men who participated in the experiment did so based on their own free will after being informed of their medical conditions. However, today's standard of informed consent would reject this argument.

As Terry (2011) explains in *Clinical Research for the Doctor of Nursing Practice*, the definition of informed consent is boiled down to the process of communicating the research's ratio of risk to benefit to the potential participant. Potential risks are defined as physical harm, pain, embarrassment, loss of privacy and loss of time, to name a few. It is important to clarify that informed consent can only be given when a person with the capacity to make decisions exercises this power without force, fraud, deceit or any type of coercion (Terry, 2011). The Tuskegee men were told that they were being provided the most effective treatment. Additionally, and perhaps most importantly, the men were not provided with the appropriate risk to benefit ratio regarding their involvement in the study. They were simply

told they had bad blood and they had to choose between suffering in poverty or allowing the federal government to provide free medical treatment.

Would full knowledge of their illness have affected the men's willingness to participate in the study? Would they have justified the risks in the same manner as the PHS and concluded that the potential benefits are greater than the risk to their life? We don't know how many men would have volunteered for the study had they been provided full disclosure. While there is no guarantee that the men would have received superior medical treatment if they had been told they had syphilis rather that bad blood, the Tuskegee men should have been informed about the true nature of the study and provided an opportunity to withdraw in 1947 when an American tribunal established the Nuremberg Code and the principle of informed consent.

Federal Guidelines Ensure Informed Consent and the Establishment of the Institutional Review Board

The U.S. federal government no longer relies solely on the researcher to appropriately apply Hippocratic principles to their human research experiments. Today, federal guidelines must be met before the government will subsidize human research projects. In 1981, the HHS adopted formal regulations to govern all human research conducted by its personnel. These federal regulations now stipulate that participants in a research study have specific rights, which include:

1. The right to be informed of both the nature and the purpose of the research;
2. The right to receive an explanation of the procedures that will be followed and any drug or device that will be used during the research;
3. The right to receive any explanation of benefits that may be expected from the research;
4. The right to receive a disclosure of any procedure, drug, or device that could be used during the research that could benefit the participant, as well as their potential risks and benefits;
5. The right to receive information on forms of treatment available to the participants after the research project is concluded, if complications occur during the study;
6. The right to ask questions regarding the research study or any procedure involved in it;
7. The right to be told that consent to participate in the research may be withdrawn at any time, and that the participant may withdraw from the project without consequences;
8. The right to receive a copy of any signed and dated written consent form that was issued during the course of the study; and
9. The right to decide whether to consent to participate in the research without any type of force, fraud, deceit, duress, coercion or other influence being applied to pressure the subject (American Association of Critical Case Nurses, 1999).

It is evident that HHS' regulations are almost identical to the Nuremberg Code, which suggests that the U.S. government's ethical principals in 1981 were consistent with the principles of the American-led military tribunal that established the Code in 1947. However, it was thirty-four years before the government applied these standards to human research in the U.S.

> *Note 3*. The Federal Policy for the Protection of Human Subjects or the "Common Rule" is published as 45 CFR Part 46 in 1991, and is codified in separate regulations by 15 Federal departments and agencies (American Association of Critical Case Nurses, 1999; Terry, 2011). Although it is not a part of the Nuremberg Code, HHS regulation number four would have been particularly useful to the Macon County men during the Tuskegee Study. Many of the Tuskegee men likely would have survived if they had been informed of the penicillin treatment when it became available.

Overseeing the Application of Informed Consent through Institutional Review Boards

Part of HHS' Policy for the Protection of Human Subjects was the establishment of Institutional Review Boards (IRB). The IRB oversees the application of HHS' informed consent regulations. Every institution that receives federal funding for research involving human research must create an IRB and appoint its members. The guidelines require that an IRB be composed of at least five members, one of whom must be a disinterested party who is not affiliated with the institution. The institution's IRB must review all research that involves human subjects either conducted at the facility or sponsored by the institution (Terry, 2011). Most healthcare studies conducted in the U.S. currently are approved by an IRB because, in addition to the federal requirement for an IRB review before federal funding is awarded, many private funding agencies and most biomedical journals require an IRB review before human research is conducted. Also, most universities and healthcare institutions require IRB approval in order to avoid liability as research is implemented (Olsen & Mahrenholz, 2000).

An institution's IRB must look for specific conditions to be fulfilled before a research proposal can be approved. A human subject research proposal must have:

1. Minimal identifiable risks to human subjects;
2. Equitable selection of human subjects;
3. Appropriate documentation of informed consent from all participants;
4. Appropriate monitoing of data to ensure safety of subjects; and
5. Provision for ensuring privacy of human subjects and confidentiality of data gathered (O'Sullivan & Rassel, 1999)

Each institution will develop its own IRB applications. The rights of the human subjects are considered to be paramount during an IRB evaluation. Therefore, the IRB will evaluate a proposal based on several areas, which include 1) whether the consent form

addresses concerns such as deceptions of the participants, 2) presentation of the purpose of the research, 3) the costs to the subjects, 4) benefits and risks to the participants, 5) protection of confidentiality, 6) a point of contact for participants who have questions, and 7) an explanation of how the results of the study will be used. The IRB application usually requires a brief statement of the study's hypothesis, research question(s) and purpose (O'Sullivan & Rassel, 1999).

To guard against coercion, or the perception of coercion, the IRB requires information about the potential subjects to be included in the study proposal. This will include who they are, how they will be recruited, how many contacts will be made with each subject and the length of each contact, as well as any payment that will be given to participants. The IRB is particularly interested in the inclusion of subjects who have been identified as belonging to a vulnerable population, such as children, infants, prisoners, or the mentally handicapped (Kamienski, 2000).

The Federal Government's Progression of Human Research Ethical Considerations

The IRB's interest in the details regarding the experiment's human subjects suggests a significant departure from the ethical concerns of mid-century U.S. physicians. The government's requirement that an IRB review, with particular interest, any research that involves children, prisoners or the mentally handicapped is a dramatic shift from the government's concerns during the Guatemala Experiment and the post WWII Japanese human research information exchange. This reveals a significant development in ethical principles. The perceived 1932 HHS policy of "by any means necessary to advance the greater good" has been replaced by a 1981 policy that strongly considers human rights and requires that a completely informed subject provide uncoerced consent to the study. During the later part of the twentieth century, the U.S. begins to place a greater emphasis on the principle of informed consent and recognizes the ethical dilemmas associated with performing medical research on individuals who do not have the capacity, or the freedom, to provide consent.

A Doctrinal Examination of Human Research Ethics in U.S. Courts

"…Unless the law winks occasionally, you have no progress in medicine."
Dr. Thomas Rivers, Rockefeller Institute for Medical Research Hospital, New York, (Gorski, 2010)

The U.S. Courts have developed a theoretical division between therapeutic treatment whose effects are intended to cure or treat a particular ailment, and nontherapeutic procedures. Medical experiments regarding therapeutic procedures are traditionally viewed as a type of therapy and the courts' primary concern has focused on the subject's informed consent. In this regard, principle one of the Nuremberg Code, although rarely cited, became the primary justification for therapeutic experimentation. On the other hand, nontherapeutic treatment has been viewed as the only kind of true medical experimentation and, thus, the only kind of research activity to which the Nuremberg code applies (Annas, 1991).

Judicial Examination of an Experimental Therapeutic Procedure

The first U.S. case to make use of the Nuremberg Code was *Kaimotiz v. Michigan Department of Mental Health*. This Michigan Circuit Court case addressed a form of psychosurgery that involved brain surgery intended to relieve severe and otherwise intractable mental or behavioral problems (*Kaimotiz v. Department of Mental Health for the State of Michigan*, 1973). This case drew national attention because of the then current political debate surrounding a therapeutic treatment that involves the destruction of normal brain tissue for the purpose of modifying undesirable behavior. In 1972, two psychiatrists had obtained state funds to study the effects of amygdalotomy (the destruction of a portion of the brain's limbic facilities) and cyproterone acetate (an orally administered drug that inhibits aggression by blocking testosterone) on male aggression in prison and mental health facilities (Annas, 1991; Cyproterone, 2010). The goal was to modify antisocial behavior so that inmates could be safely released to the community (Annas, 1991).

Both a scientific review committee and a human rights committee approved the study. A suitable candidate had been found in a Michigan state hospital. He had been held in the hospital as a criminal sexual psychopath for seventeen years, having been charged (but never tried) for murder and rape. Although he and his parents had signed a detailed consent form, a lawsuit was commenced by a public interest group to halt the proposed experiment. The court focused on whether involuntarily confined individuals could ever legally consent to experimental brain surgery. In deciding how to answer this question the court relied upon the Nuremberg Code for "guidance." The court found that the Nuremberg Code established that an individual must be so situated as to be able to exercise free power of choice without any element of force, fraud, deceit, duress, or other form of restraint or coercion. Additionally, the individual must have sufficient knowledge and comprehension of the subject matter to enable him to make an understanding decision. The court concluded that the candidate could not give voluntary, competent and informed consent for the procedure and the experiment could not be performed (Annas, 1991). Although the Michigan court's decision addressed whether confined individuals could ever be capable of providing consent to such and invasive experimental operation, it was the first time a U.S. court relied on the Nuremberg Code to establish the principle of informed consent.

Judicial Examination of Nontherapeutic Experiments

In 1981, several former U.S. soldiers and their families brought a suit alleging that in 1953 the soldiers were ordered to stand in a field without protection from radiation when a nuclear device was detonated in a Nevada desert. As a result of the exposure, the plaintiffs were exposed to toxic amounts or radiation and some of them had died from cancer (*Jaffee v. United States*, 1981). The U.S. Court of Appeals for the Third Circuit decided that the plaintiffs' claim for compensation for an intentional and unconstitutional tort was barred by the *Feres* doctrine, which held that service members injured in the course of activity incident to service may not sue for additional compensation under the Federal Tort Claims Act (*Feres v. United States*, 1950; *Jaffee v. United States*, 1981). A dissenting opinion in the *Jaffee* opinion expressed concern about ordering soldiers to stand near a nuclear explosion without radiation protection and found the court's decision to be contrary to basic human rights. Additionally, they found the actions of the U.S. government to be a violation of many international standards, including the Nuremberg Code. The dissenting opinion stated that

the international consensus against involuntary human experimentation is clear and should overrule the *Feres* doctrine. (*Jaffee v. United States*, 1981; Annas, 1991). It should be noted that any U.S. POW, or their family, would likely be barred under the same doctrine for any injuries they suffered due to the Japanese Imperial Army's human subject experiments during the Second World War.

Three years later, a federal district court judge treated the Nuremberg Code as a discussion document lacking legal enforcement in the U.S. In 1984, former Navajo uranium miners and their survivors brought suit against the U.S. government requesting compensatory damages for injuries suffered as a result of exposure to radiation during uranium mining in federal mines. Among the allegations was that the PHS had conducted a prospective epidemiological study of a cohort of Navajo uranium miners form 1949 to 1960 to order to determine if they were at increased risk for cancer, lung disease and other problems. The PHS did not tell the miners why they were being examined. The miners had an annual physical exam in 1950, 1951, 1953 and every three years thereafter until 1960. They were told that the exam was part of a study of the health of uranium miners, but were not warned about the suspected risks of uranium mining (*Begay v. United States*, 1984).

Similar to the PHS' Tuskegee Study, the plaintiffs argued that the study was conducted in violation of the miners' human rights (Annas, 1991). In response, the court held that the study's protocol and the conduct of the PHS were consistent with the medical ethical and legal standards of the 1940s and 1950s. Since the PHS was only gathering data and was not experimenting on human beings, the decision not to tell the Navajo miners about the risk of uranium radiation was a discretionary decision and not covered by the Federal Tort Claims Act. The court went on to say that the PHS decision not to inform the research subjects of the risk of continued exposure to uranium was justified based on considerations of political and national security feasibility factors (*Begay v. United States*, 1984). The similarities between PHS' role in the Navajo miners observation experiment the Tuskegee Study are disturbing. Both studies involved a government agency observing an illness or suspected illness in a minority class of citizens, neither group was informed about the nature of the study and the risks to their health; and, moreover, the PHS' non-disclosure was supported by the government.

The types of experiments in which American judges have used the Nuremberg Code as an ethical guide for establishing standards have involved nontherapeutic experiments often conducted without consent. The courts have concluded that many, though certainly not all, of these experiments were justified by national security considerations and the Cold War. This is consistent with the government's justification for not prosecuting the Japanese in exchange for their research. National security and the justification for wartime experimentation expressed by the U.S. Army in *Jaffee* and the PHS' Navajo studies were substantially similar to the defenses presented by the Nazi physicians at Nuremberg (Annas, 1991).

Nuremberg Code Legal Duty to Care as Applied to U.S.

More recently, a Maryland court recognized the difficult issues that arise when the judiciary is asked to balance the law, ethics and nontherapeutic research studies. The case of *Grimes v. Kennedy Krieger Institute Inc.* marked the first time a state's appellate court directly addressed the ethics of allowing a parent to provide consent for a study that provides no

direct benefit for the child. The Maryland court issued a unique opinion that relied on the ethical standards established by the Nuremberg Code to create a legal relationship between researchers and their subjects that included a duty of care while citing the sacrosanct notion of voluntary consent (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001).

The decision addressed two negligence cases in which the plaintiffs were young children involved in a study conducted by the Kennedy Krieger Institute (KKI), an affiliate of John Hopkins University. The plaintiffs allege that they received lead poisoning or were subjected to the risk of receiving lead poisoned as a result of participating in KKI's research study. KKI's study was designed to determine the relative effectiveness of different methods of lead paint abatement. The study was funded by the Environmental Protection Agency (Glantz, 2002). The study required homes in low-income, urban areas to undergo partial lead paint abatement and asked landlords to rent these premises to families with young children. The families were encouraged to remain in the houses so that the children's blood could be tested for lead over time. Only low-income children were involved as subjects. Their parents were enticed with nominal compensation ($5–$15), food stamps, and other items. The research protocols were approved by Johns Hopkins University Joint Committee on Clinical Investigation (the institution's IRB). The researchers had the families sign consent documents agreeing to participate in the study, however, the consent form did not indicate that the study involved exposing the children to lead and testing their blood to observe the effects of exposure. The KKI researchers knew that the plaintiffs had developed a dangerously elevated level of lead in their blood and failed to notify the parents in a timely manner (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001; Glantz, 2002).

The trial court granted KKI's motion for summary judgments and dismissed the case deciding that the researchers did not have a duty to warn the plaintiffs (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001). The specific issue before the appellate court was, as a matter of law, does a research entity conducting a nontherapeutic study have a duty to warn a volunteer regarding the dangers present when the researcher has knowledge of the potential for harm to the subject (Glantz, 2002)?

The court of appeals reversed the trial court's ruling, deciding that governmental regulations can create duties on the part of researchers towards human subjects out of which special relationships can arise. The court explained that the Constitution's promise of due process of law guarantees at least compensation for violations of the principle stated by the Nuremberg Military Tribunals that the voluntary consent of the human subject is absolutely essential to satisfy moral, ethical and legal concepts (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001).

The Nuremberg Code specifically requires researchers to make known to human subjects all inconveniences and hazards reasonably to be expected, and the effects upon their health or person which may possibly come from their participation in the experiment. The breach of obligations imposed on researchers by the Nuremberg Code might well support tort actions sounding in negligence. The court partially relied upon George J. Annas' (1991) conclusion that the Nuremberg Code is the most complete and authoritative statement of the law of informed consent to human experimentation and, as a part of international common law, may be applied in both civil and criminal cases, by state, federal and municipal courts in the United States (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001).

The Maryland court's ruling that the Nuremberg Code established a special relationship imposing ethical duties on researchers who conduct nontherapeutic experiments on human subjects was the first time any U.S. court has so explicitly adopted the Nuremberg Code as a source of legally enforceable standards. John Hopkins' IRB approval of a study that exposes low-income children in urban areas to lead poisoning raises significant concerns regarding the objectivity of the IRB process and application of federal regulations that have been established to protect human research subjects. The court addressed this problem in its opinion.

> It is clear to this Court that the scientific and medical communities cannot be permitted to assume sole authority to determine ultimately what is right and appropriate in respect to research projects involving young children free of the limitations and consequences of the application of Maryland law. The Institutional Review Boards, IRBs, are, primarily, in-house organs. In our view, they are not designed, generally, to be sufficiently objective in the sense that they are as sufficiently concerned with the ethicality of the experiments they review as they are with the success of the experiments (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001).

The researcher's duty is not extinguished by the consent of a research study after IRB review. The duty owed to a vulnerable research subject is independent of an IRB review (*Grimes v. Kennedy Krieger Institute, Inc.*, 2001). Although *Grimes* does not establish a legal precedent outside of Maryland, it has been subsequently cited by federal district courts in numerous circuits. Most importantly, it provides valuable ammunition for the American judiciary when the IRB review process has failed and a nontherapeutic research experiment has caused harmed to its subjects.

Considering the Tuskegee Study in Light of Today's Regulations

If we could suspend what we know about the outcome of the Tuskegee Study and compare it to today's human research review process, it would be interesting to identify at which point in the process the study would be terminated. Ideally, the study would not pass an initial IRB review since its purpose was to observe patients while they endured a fatal disease without providing effective treatment once a cure was discovered. In order to meet the standards established in Title 45 CFR Part 46, the government physicians would have been required to tell the men that the purpose of the study was to monitor the progress of untreated syphilis. The subjects would also be informed about the current and alternative treatments for syphilis. Among other things, the men would have been counseled about the emotional, psychological and physical effects of living with untreated or passively syphilis. Additionally, a consent form, drafted for their appropriate education level, would be given to subjects to take home and review.

Conclusion

Although it has been eighty years since the initiation of the Tuskegee Study, this article has demonstrated that it was not an isolated occurrence for its time. It is clear that basic human rights protections concerning medical experimentation were violated both at home and abroad. Worse still, that populations least able to protect themselves were

purposefully targeted using loose ethical justifications that applied non-uniformly to the advantage of the medical research community.

Over the past eighty years, all branches of the U.S. government have been involved, in some way, with either the perpetration of ethically questionable research behavior or mistakenly relying upon the research community to internally monitor and apply individual ethical standards of care and informed consent. Therefore, constant vigilance is required from the executive, legislative and judicial branches of our government to ensure human medical research is conducted in a consistently ethical manner. The executive branch demonstrated its role in ethical human research policy formation by frustrating and even declining the prosecution of members of the Japanese Imperial Army in exchange for information they obtained from medical experimentations performed on prisoners of war and civilians during WWII. Today, the executive branch appears to recognize its duty to adhere to human research standards as demonstrated by President Obama's Bioethics Committee report which exposed the U.S.'s role in unethical human research in Guatemala and the president's formal apology to the nation of Guatemala. The judicial opinions in this article reveal the necessity for constant judicial oversight of questionable research practices. Although the judicial reasoning differs, the courts play a crucial role in defining informed consent and the fiduciary relationship between researchers and their subjects. The legislative branch could have ended the Tuskegee Study much sooner had they adopted the Nuremburg Code in 1948. Its delayed ratification had dire consequences in shaping the questionable policies that rationalized both the Guatemala Experiment and the Tokyo Trials exchange in the name of medical advances and national security. The legislative branch must continue to review and update the National Research Act to ensure its effective application by U.S. government agencies.

> *Note 4.* The authors recognize that there continues to be controversy surrounding the Executive Branch and human research especially in light of allegations that drug companies have been allowed to illegally experiment on wounded soldiers in Iraq (Edwards, 2011).

The findings of this article have important implications for moral and ethical decisions that guide human research practitioners. The past eighty years have revealed that we are not completely removed from the medical atrocities conducted by Nazi Germany, the Guatemala Experiment or the Tuskegee Study. Through coordination, oversight and vigilance the United States can adhere to and enforce the necessary regulations that will prevent us from sliding down the slope of unethical justifications that have lead us far afield in our recent past.

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When Disaster Strikes: Humanism in Medicine after the Earthquake in Haiti

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Abstract

Natural disasters contribute to significant financial, environmental and human losses but at the same time provide an opportunity for people from a wide range of backgrounds to work together toward the common goal of alleviating human suffering. The earthquake that took place in Haiti in January 2010 devastated Haiti's government and public health infrastructure and prompted an unprecedented international response. Volunteers from around the world traveled to Haiti in order to provide much needed humanitarian assistance and disaster relief (HADR). The United States government launched a prominent relief effort to the earthquake known as *Operation Unified Response*. The USNS *Comfort*, a Mercy class hospital ship, was deployed to Haiti. The *Comfort* served as the tertiary care medical center for the region and offered many services not available anywhere else on the island. A multidisciplinary Healthcare Ethics Committee (HEC) and a comprehensive interpreter department were formed. The HEC and the interpreter department served to facilitate the superimposition of the large tertiary care medical center on the impoverished island nation of Haiti, helping to bridge the cultural gap between the medical practitioners and the Haitian

patients. In this paper the challenges of delivering healthcare in these austere circumstances are reviewed, recommendations for overcoming challenges are offered, and guidance for the execution of future HADR missions are presented.

Keywords: Earthquake, disaster, humanitarian assistance, disaster relief, ethics

Introduction

The 1980 United States Rockefeller Commission on the Humanities described the humanities in its report entitled *The Humanities in American Life*:

> Through the humanities we reflect on the fundamental question: What does it mean to be human? The humanities offer clues but never a complete answer. They reveal how people have tried to make moral, spiritual, and intellectual sense of a world in which irrationality, despair, loneliness, and death are as conspicuous as birth, friendship, hope, and reason (Topf, 1981).

The 2010 earthquake in Haiti provided an opportunity for people around the world to come together and provide humanitarian assistance to a country in great need. Disasters, and the disaster response that follows, have a tendency to bring people together to work for the greater good. The humanitarian assistance provided after the earthquake in Haiti has gone far beyond saving the lives of people who suffered obvious "earthquake-related" injuries like those who were crushed by buildings or stuck under rubble. Indeed the worldwide humanitarian effort has been a movement to maximize the quality of life of the Haitian people, including those with the seemingly invisible wound of psychological trauma. Many volunteers have remained in Haiti to help build and rebuild a country in great need, and they have been able to offer immediate assistance as new problems like the cholera epidemic (MMWR, Dec 2010) have presented.

The 7.0 moment magnitude (Mw) earthquake that took place in Haiti on January 12, 2010 is considered the deadliest natural disaster in the history of the Western Hemisphere (Etienne et al., 2010; USGS, 2010). The earthquake decimated Haiti's government and public health infrastructure and it demonstrated the vulnerability of underdeveloped countries to natural disasters. It was immediately followed by an unprecedented international response which has been one of the most impressive humanitarian assistance and disaster relief (HADR) efforts in recent history. Some aid workers provided assistance within the first 24 hours of the disaster (Kidder, 2010; Jaffer, 2010), while others gradually arrived over the days (Kreiss et al., 2010; Amundson et al., 2010), weeks and months following the earthquake. One of the most prominent and well-publicized responses to the earthquake in Haiti came from the United States Navy. The United States government deployed the United States Naval Ship (USNS) *Comfort*, as part of *Operation Unified Response*, to Haiti to provide much needed HADR. When the USNS *Comfort* arrived in Haiti, it served as the tertiary care medical treatment facility (MTF) in the region and offered many services not available anywhere else on the island (Amundson et al., 2010).

While en route to Haiti the *Comfor*t staff took measures to ensure they would be adequately prepared to address the myriad of maladies they might encounter upon their

arrival in Haiti. That included making sure equipment like the CT scan, hemodialysis and roentgenogram units (X-rays) were functioning properly. That also included making sure the laboratories, wards, and pharmacies were appropriately stocked with medications and supplies that would be necessary to treat the patients who would soon board the ship. In order to facilitate the superimposition of the large tertiary care medical center on the underdeveloped island nation of Haiti, a multidisciplinary Healthcare Ethics Committee (HEC) was formed along with an interpreter department. The two entities were instrumental in bridging the cultural gap between the United States healthcare providers and the Haitian patients and thereby contributed immensely to the success of Operation Unified Response. The work of the USNS Comfort in Haiti after the earthquake has arguably set the standard for how to carry out HADR missions.

The USNS *Comfort* and Haiti

The USNS *Comfort* is a mercy-class hospital ship with a total patient capacity of 1,000 beds, which includes 80 intensive care unit beds. There are twelve operating rooms, a laboratory, a blood bank, and a radiology department which includes CT scan, roentgenograms and ultrasound capability. The primary mission of the MTF in the USNS *Comfort* is to provide a mobile, flexible, and rapidly responsive afloat medical capability for acute medical and surgical care in support of amphibious task forces, Marine Corps, Army and Air Force elements, forward deployed Navy elements of the fleet and fleet activities located in areas where hostilities may be imminent (USNS *Comfort*, 2010). Such missions have included *Operation Desert Shield/Desert Storm* and *Operation Iraqi Freedom*.

As a secondary mission, the *Comfort* is capable of providing a full hospital service asset for use by other government agencies involved in the support of relief and humanitarian operations worldwide (USNS *Comfort*, 2010). Domestically, the *Comfort* was deployed for *Operation Noble Eagle* which was in direct response to the terrorist attacks on September 11, 2001 during which the *Comfort* offered medical services at Pier 92 in midtown Manhattan. The *Comfort* was again deployed to offer humanitarian assistance in the Gulf Coast recovery efforts after Hurricane Katrina.

The *Comfort* has made numerous trips to Haiti including *Operation Sea Signal* in June 1994 and *Operation Uphold Democracy* in September 1994. In addition, the *Comfort* has given humanitarian assistance to Haiti as part of the Continuing Promise Missions that took place in 2007 and 2009. During those missions, the *Comfort* sailed to numerous countries throughout Central America, South America and the Caribbean and offered medical care and surgical procedures in an effort to promote social justice in the region. This long-standing relationship between the USNS *Comfort* and the people of Haiti made the *Comfort* a familiar entity and may have served to partly alleviate the terror that many of the patients from Haiti were experiencing after the earthquake. Through the various missions described above, many of the physicians, nurses, and other staff had prior opportunities to become familiar with the Haitian people and culture. In addition, the Red Cross that is brandished on the many surfaces of the ship may have also helped to decrease the angst and terror being experienced by the patients. The Red Cross represents the international humanitarian effort to protect human life and health, to ensure respect for all human beings, and to prevent and alleviate human suffering (American Red Cross, 2010) (Figure 1).

Figure 1. The Operation Unified Response logo painted above the flight deck of USNS *Comfort*.

Operation Unified Response marks the only time in history that the USNS *Comfort* has ever operated at or near its capacity. During *Operation Unified Response*, the USNS *Comfort* was deployed with physicians from many specialties including internists, pediatricians, pulmonologists/intensivists, nephrologists, cardiologists, infectious disease specialists, neurologists, a dermatologist, a psychiatrist and numerous additional behavioral health specialists. Surgical specialties on the ship included neurosurgery, trauma surgery, plastic surgery, pediatric surgery, urology, ophthalmology, obstetrics/gynecology, and orthopedics. There were also dentists, physical therapists, and optometrists on the ship who all added to the overall success of the mission. The staff of the *Comfort* included both military and civilians. The civilians on the ship were both governmental (e.g. USAID) and nongovernmental (eg. Project Smile, Orthopedic Trauma Association, Project Hope, American Red Cross) as well as academic institutions (eg. Harvard University, University of Michigan, Johns Hopkins).

Healthcare Ethics Committee (HEC)

International humanitarian response to crises employs 210,000 people and accounts for nearly $15 billion in spending globally each year (Walker et al., 2010). Just as there are rules of engagement for war (Hensel, 2007), there should be clear rules or guidelines for providing humanitarian assistance and disaster relief to foreign countries and communities. As the global community gets closer and more interdependent, and as travel to the many corners of the world gets easier having these rules or guidelines in place will prove quite beneficial. It will be important for experts in the area of HADR to go over best practices and lessons learned from prior disasters so that there can be process improvement. The case has been made for professionalization of HADR (Walker et al., 2010). The professionalization of HADR will require cooperation from United Nations forces, military and civilian government agencies, academic medical centers and the non-governmental organizations that

have consistently been a strong force in HADR missions around the world. As experts review the successes and pitfalls of the Tsunami relief effort in Indonesia (Kongsaengdao et al., 2005; McGuinness et al., 2006; Wong et al., 2006; Morrow & Llewellyn, 2006), the earthquake relief effort in Haiti (Etienne et al., 2010; Zoraster, 2010; Lin et al., 2010) and other disaster relief efforts some common themes will emerge and soon the blueprint will be laid out so that the next time disaster strikes; a rapid, efficient and well-coordinated international relief effort can be executed.

As the USNS *Comfort* was en route to Haiti, the multidisciplinary healthcare ethics committee was formed in accordance with Navy Medicine Policy, BUMEDINST 6010.25, and Establishment of Healthcare Ethics Committees. The HEC consisted of a psychiatrist, a surgeon, two neurologists (one adult and one pediatric), two nurses, a nurse practitioner, a nurse anesthetist, a hospital corpsman (medic), an attorney, a chaplain, a social worker and a healthcare administrator. Three members of the HEC, including the HEC chairman, were naturalized US citizens of Haitian descent. These members had a great deal of insight about the people, the culture and the customs in Haiti. All three spoke Haitian-Creole fluently and were able to interview patients and families without the aid of translators. One member of the HEC was from the United States Agency for International Development (USAID), an organization that has a great deal of experience working with underdeveloped countries such as Haiti (Figure 2).

Figure 2. Healthcare Ethics Committee on USNS *Comfort* during *Operation Unified Response*. Front Row (L to R): LT Elizabeth Schuller, LT Andrea Hernandez, LCDR Mill Etienne, LTJG Joseph Fiscus. Back Row (L to R): CDR David Oravec, CAPT Fleurette Etienne, HM1 Melissa Leonard, CDR Janis Carlton. Missing: Dr. Clydette Powell, Ms. Magaly Polo, CDR Anand Kumar, CAPT Mark Larsen, CAPT Nora Bertschy.

The HEC convened multiple times prior to arriving in Haiti and considered possible ethical challenges that may be encountered during the mission. Such challenges included appropriate allocation of resources when demand for services exceeds the capacity of the *Comfort*, culturally appropriate disposal of patients who expire on the ship, criteria for blood transfusions, and the consent process for displaced children, among others. In order to stress the importance of embracing cultural competence when offering disaster relief in the form of healthcare to a foreign country, the HEC used two sociocultural applications of the basic ethical principles of autonomy, beneficence, non-maleficence and justice as guiding principles throughout the mission. The two sociocultural contexts (see Figure 3) are:

1. Respect for communities, cultures and traditions
2. Respect for sovereignty of the Host nation

When these socio-cultural applications were applied to the many ethics consults presented to the HEC, often the most complex of ethical dilemmas came to an acceptable resolution to all involved parties. These two tenets were considered of paramount importance as the *Comfort* staff offered aid to the people of Haiti. The HEC believed that respecting the communities, cultures and traditions of the local population was a way to increase the likelihood of the USNS *Comfort* developing into a culturally competent healthcare network. This model of care stressed the importance of giving the patient the best possible healthcare experience. It allowed the *Comfort* staff to not only offer high quality healthcare but rather to offer the highest quality culturally appropriate healthcare to the Haitian people at a time that the Haitian population was experiencing an unprecedented amount of terror from a natural disaster. This form of healthcare delivery assisted the *Comfort* staff in resolving issues when the values of the USNS medical community conflicted with the values of the individual patients, families or the larger non-medical community. Respect for communities, cultures and traditions were accomplished through staff education both while en route to Haiti and while in Haiti. Additionally, insight provided by the members of the HEC who were of Haitian descent and insight from members of the HEC who had prior experience working in Haiti proved to be quite helpful. Respect for sovereignty of the Host nation was achieved by having regular communication with the Haitian government, particularly with the Haitian Ministry of Health which is known as the Ministère de la Santé Publique et de la Population (MSPP).

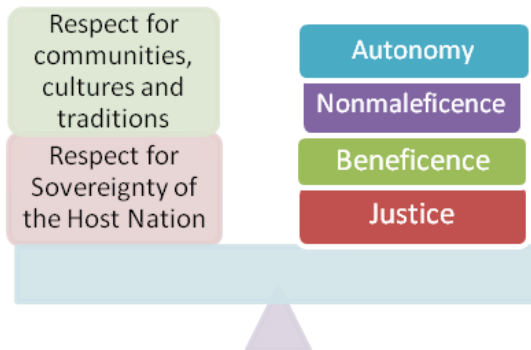

Figure 3. Healthcare Ethics during HADR.

Found in Translation

Language translation is a humanistic art that requires the person translating to have an in depth understanding of the two cultures being bridged. A good translator does not merely string together a series of words into sentences to be recited verbatim as dictated, but rather a good translator takes a message and a sentiment from one culture and presents it to the other culture in a manner in which it takes on meaning and can have the intended impact. Indeed many have become familiar with the term "lost in translation" which occurs because information may be lost when one does a direct translation of text from one language to another which leads to a failure to convey the original meaning of the message. By having translators knowledgeable of the language and culture of the patients, there may be a greater likelihood of preserving the messages being passed between physician and patient.

Given that only one physician on the *Comfort* was fluent in Haitian-Creole, with a few other practitioners fluent in French; it was clear early on that there would be a significant problem in the delivery of emergency care if this impediment to communication was not addressed. A key element to having a successful mission would be for the practitioners to be able to effectively communicate with the patients. To address this issue, Southern Command (SOUTHCOM) called for service members who speak Haitian-Creole to be deployed as part of *Operation Unified Response* on the USNS *Comfort* so they can assist with translation.

On the first full day in Haiti there were only twelve people on the ship (military and civilian) capable of translating, with only three of them being full time translators. Many workers had to be pulled from their regular work in order to translate which meant a longer work day for those individuals. Two days after dropping anchor in Haiti's shores there were 57 naval Haitian-Creole interpreters. Throughout the course of the mission there were 86 Haitian-Creole interpreters who represented 39 different US Navy and Marine Corps commands, however the most military translators at any one time was 76. There were

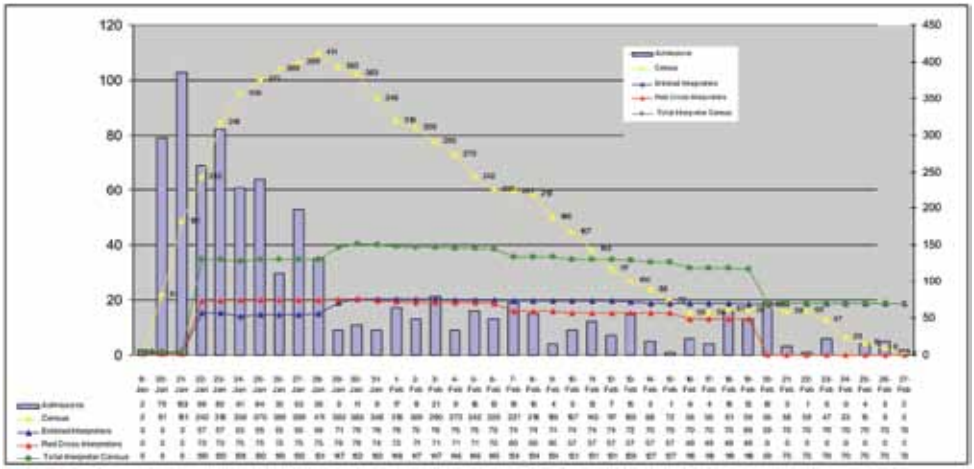

Figure 4. Admissions/Census versus Number of Interpreters. Bar graph on Left Axis. Line graphs on the Right Axis. (Graph courtesy of LT Renardis Banks)

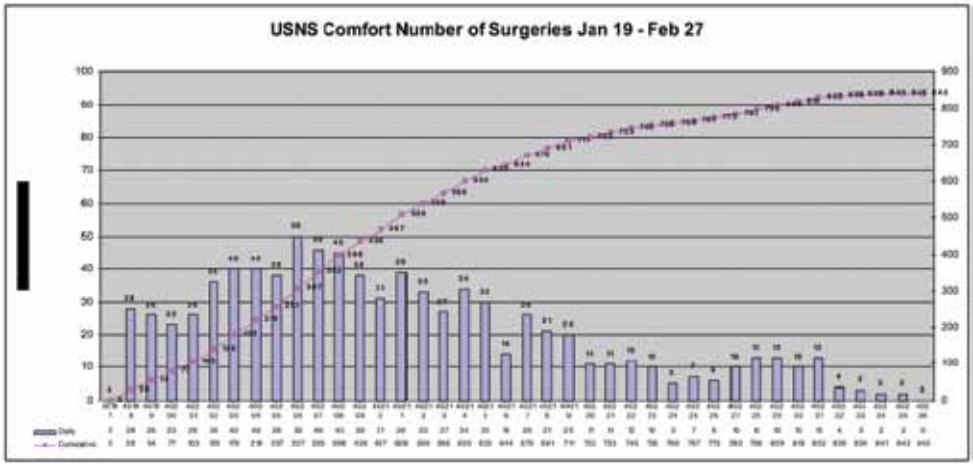

Figure 5. Cumulative Number of Surgeries by Day. Bar graph on the left axis and line graph on the right axis. (Graph courtesy of LT Renardis Banks)

also up to 76 Haitian-Creole translators from the American Red Cross. There was adequate translator support to have translators assigned to the casualty receiving area, the intensive care units, wards, operating rooms, post-anesthesia care units, clinics and other patient care areas 24-hours a day. Although the American Red Cross volunteers were not familiar with the ship environment, their military counterparts helped them to quickly adapt to the battle rhythm of the ship. Given the large size of the translator program, it was made into its own department for the duration of the mission. The robust translator department also made it more feasible to obtain informed consent for the over 800 surgical procedures performed throughout the mission (see Figures 4 and 5).

The majority of translators on the USNS *Comfort* were of Haitian descent so they were knowledgeable of the Haitian people and culture. This helped facilitate a good physician-patient relationship and it may have helped patients to feel more comfortable with the hospital environment. At the same time, given that so many of the translators were of Haitian descent, there was a significant concern about the translators ability to successfully execute their job as translators given that many of them had family and friends who died, were injured or were missing after the earthquake. Many of them were being encouraged by their families to go into Haiti and look for their loved ones who remained missing. The *Comfort* leadership recognized that people of Haitian descent on the ship were at risk of meeting a patient on the *Comfort* who may be their friend or family member. Behavioral health services were made available to the translators throughout the mission and there were forums in which the translators were able to voice their concerns and discuss personal issues. As the mission progressed, the translators demonstrated strength, courage and resilience. They were able to execute their jobs with a high level of professionalism and were frequently praised by the providers for the great work that they were doing. It was clear that the translators on the *Comfort* went far beyond the traditional role of translators because they wanted to do all they could for their native country that had just suffered a disaster of epic proportions.

Earthquake Related

At the time of the earthquake Haiti was recovering from a tropical storm and three major hurricanes from 2008 (Etienne M et al., 2010); it was the poorest country in the Americas with an estimated GDP of $12 Billion purchasing power parity (CIA World Fact Book, 2010) and childhood immunization rates were between 50–60% for Diphtheria, Pertussis, Tetanus, Polio and Measles (UNCF, 2010). There were patients living with chronic diseases that have gone untreated and the arrival of the *Comfort* and other medical missions was seen as an opportunity to see a physician and initiate therapy.

Throughout the mission in Haiti, there were many who believed that the USNS *Comfort* should only be treating patients with "earthquake-related" injuries. If the scope and goal of the disaster relief was simply to provide emergency medical and surgical care, then the primary role of the *Comfort* would have been to treat patients who had trauma related to crush injuries from having buildings and other structures collapse on them. Rather the mission of the MTF on the *Comfort* was to provide humanitarian assistance and disaster relief in the form of healthcare. With that stipulation, there became a greater range of diagnoses than would fall under the umbrella of being "earthquake-related."

Case Presentation

As an illustrative example, consider the case of NM. NM was an 11 month old boy at the time of the earthquake in Haiti. NM was born full term and was the product of a normal spontaneous vaginal delivery. At approximately 3 months of age, NM had gradual increase in his head circumference. He was evaluated by numerous doctors in Haiti who told his parents they would not perform any intervention. The earthquake struck and left the family homeless. On the day that the USNS *Comfort* arrived in Haiti, NM was brought to Terminal Varreux, an access point for patients to get on the USNS *Comfort*, by his mother. After evaluation by pediatricians and neurologists on the *Comfort*, it was determined that NM had massive hydrocephalus with a head circumference of 72cm. He had numerous signs suggesting that the hydrocephalus was putting pressure on his brainstem and he may die if he did not receive a ventriculo-peritoneal shunt (VP shunt) to decrease the amount of fluid and pressure in his brain.

Although the procedure would take less than an hour, there was concern amongst the medical staff that if the USNS *Comfort* started doing elective procedures for non-earthquake related problems; the hospital ship could be there indefinitely. Additionally the use of the *Comfort's* resources for non-earthquake related medical problems could be viewed as a misallocation of resources given that the resources used on such a patient could be utilized on patients who had suffered injuries from the earthquake. This was one of the first issues presented to the HEC and the management of this issue served as a precedent for the management of other similar issues throughout the remainder of *Operation Unified Response*.

The HEC convened and commented that although hydrocephalus is not earthquake related, the earthquake has had a significant impact on the quality of this family's life and this child would face more significant challenges than a child without hydrocephalus in coping in post-earthquake Haiti. With the increasing emphasis on systems medicine, the patient was looked at as a whole and his environment was a critical factor. The potential

problems with maintenance of the VP shunt were discussed with the mother including the importance of having access to a surgeon who has familiarity with VP shunts. The mother made it clear that she would be able to secure access to doctors able to manage the shunt. NM received the VP shunt and in the post-operative period he was able to grasp items with his hands and he was able to smile. NM's mother reported that she had never seen him smile before. Over the course of nine months his head circumference decreased about seven centimeters. NMs parents have commented that the gradual improvement they have seen in NM has provided a great deal of hope for the family and neighbors in post-earthquake Haiti. Nine months after the shunt was placed, NM developed a hydrocele testis which was a complication from the VP shunt. This was managed successfully by a local surgeon. A repeat CT scan of the brain showed mild improvement from the CT scan that was performed on the USNS *Comfort*.

Less contentious cases were those that were expected from an earthquake like fractures of the spine, limbs and pelvis. Amputations were considered the signature wound of the earthquake; thirty-eight primary amputations were performed on the *Comfort*. The number of amputations being performed in Haiti after the earthquake had many patients concerned that practitioners were cutting off people's arms and legs without exploring all possible options. This concern was so pronounced that some patients were frightened of having x-rays done, believing that the x-ray was a prelude to amputation and that afterwards they would lose an arm or a leg (Etienne, 2011). This concern amongst the patients prompted the staff to give more detailed explanations of examinations, tests and procedures being performed on the *Comfort*.

More than 250 patients presented to the *Comfort* with significantly infected or ischemic limbs and were considered at risk of losing their lives or their limbs. One example was a young man who presented with gas gangrene in one of his limbs requiring emergent amputation. He initially refused the amputation because he was concerned about how he would perform his job as a police officer, and father, after an amputation. Once he came to understand that without an amputation death was all but certain, he agreed to have the amputation. Prior to the earthquake, there was very little written about amputations and limb prosthetics in Haiti. There has been great concern that people receiving amputations in Haiti would not be able to survive in post-earthquake Haiti, especially given that prior reports suggested that only about 25% of patients who had received amputations in Haiti went on to receive prosthetic limbs (Bigelow et al., 2004). There was great concern about the physical challenges posed by living with amputations in a mountainous country with poor roads. Even before the earthquake struck, Haiti had few rehabilitation professionals and little capacity to manufacture essential assistive technologies, including prostheses and wheelchairs (Bigelow et al., 2004; Iezzoni et al, 2010). These were valid concerns, especially with regards to children who were skeletally immature and thus may require multiple changes or adjustments in prostheses as they grow (Cummings, 2000; Abudu et al., 2006; Wilkins & Soubeiran, 2001).

In North America a competent adult who has capacity to understand his or her condition as well as the treatments being offered can refuse life-saving treatment. However when a child, who is a minor, needs a procedure which the treating physicians view as life-saving, often the courts will overrule the parents decision to reject surgery and allow physicians and surgeons to carry out the life saving treatment (Guichon & Mitchell, 2006).

This axiom proved one of the most challenging for the HEC on the USNS *Comfort*. In practicing medicine, healthcare practitioners try very hard to adhere to the supreme healthcare ethics tenet of *primum non nocere* or "first do no harm." This tenet remains as a reminder to physicians and other healthcare practitioners that human acts with good intentions may have unwanted consequences. In post-earthquake Haiti, the Haitian ministry of health asked that the aid providers not offer any treatments to the patients that Haiti would not be able to sustain once those aid providers have left Haiti. The MSPP believed that offering treatments that could not be sustained would do more harm than good.

One Haitian patient in his twenties, whose leg had been amputated on the *Comfort*, articulated his concern by explaining that although doctors on the *Comfort* may be saving the patient's lives with the life or limb procedures, there was a new problem being created by this large number of amputations. He spoke about how he is already discriminated against due to his darker skin complexion and now will be subject to even greater discrimination given his new disability. He explained that in Haiti when you are missing a leg or an arm, you may be stigmatized and perceived as weak and lazy since you are not doing as much work as other people who did not have disabilities and he added that it would be quite difficult to survive (Etienne, 2011).

Despite these valid concerns about the survivability of Haitians with amputations in post-earthquake Haiti, months after the earthquake Haiti formed an amputee soccer league which went on to compete in the International Amputee soccer world cup (International Institute of Sport, 2010), which marked their first time in this competition. Although the team did not win, it certainly provides a glimmer of hope for the people in Haiti who have suffered devastating injuries requiring amputations. Given that the signature wound of the earthquake was amputation, seeing Haitians who had amputations and had just received prosthetics compete on the world stage in a sport that requires use of the very limbs that had been amputated spoke volumes about the unrelenting spirit of survival that is present in the Haitian people.

Case Presentation

MP was an 8 year old girl who was stuck under a collapsed building for multiple days following the earthquake. After she was rescued from beneath the rubble, her parents took her to a facility on land on 21January 2010. Examination at that time revealed that her right foot was degloved and there was evidence of infection on the dorsum of the right foot and ankle. The wound was debrided, she was given Lactated Ringers intravenously and an amputation was advised. The family refused the amputation and the following day the mother presented with the child to the USNS *Comfort* to see what services would be offered. The young girl was evaluated by a pediatrician and pediatric surgeon who determined that she had a severe infection in her right leg and needs to have right below the knee (BKA) amputation. The pediatrician and the pediatric surgeon agreed that without the amputation the child would likely die. Both the child and the mother refused the amputation. The HEC was consulted.

The chairman of the HEC reviewed the patient's record and then met with the child and her mother. The mother stated that God had saved the child from the earthquake and so God will make sure that the child does not die. In that discussion the mother also

stated that the child's father gave strict instructions not to allow the child to have her leg amputated. She expressed concern, or perhaps a fear, that if indeed she did allow the *Comfort* crew to amputate the child's leg the father would abandon the family. The mother expressed concern about the social stigma of disability in Haiti and did not want her child to have to be teased or discriminated against for having a disability. She expressed concern about how she would care for a disabled child and she expressed concern about how she would obtain prosthetics for her child. Between her faith in God and the many concerns raised by the child's mother the mother remained steadfast in refusing the surgery. The child's leg was not amputated and she received maximal medical therapy in the form of antibiotics, pain management and physical therapy. She was eventually discharged.

Indeed when one juxtaposes the previously healthy 8 year old MP who needed a potentially life-saving below the knee amputation (BKA) after an earthquake against the 11 month old MT who was in need of a potentially life-saving VP shunt, the complex nature of the deliberations of a Healthcare Ethics Committee as well as the importance of having a Healthcare Ethics Committee come into full view. While the HEC was respecting the sovereignty of the host nation and demonstrating respect for communities, cultures and traditions; the 8 year old MP did not receive a surgical intervention that the medical staff and the HEC believed would save the child's life.

The two sociocultural contexts of "respect for the local communities, cultures and traditions" and "respect for sovereignty of the host nation," serve as reminders that the body providing the humanitarian assistance is working for the people and the government receiving the aid. In essence, these two principles recognize the importance of having cultural humility which has been recently described (Chang et al., 2010). In their recent paper, Chang and colleagues introduce the Humbleness curriculum which serves as a model for improving cultural competence. The humbleness curriculum emphasizes the importance of self-Questioning and critique, bi-directional cultural Immersion, mutually Active-listening, and the flexibility of negotiation. With that understanding in mind, when offering humanitarian assistance it is important to offer all services that are deemed appropriate but the people delivering the care must understand that the local people and government reserve the right to refuse that care no matter how beneficial the aid may appear.

Although the *Comfort* staff exercised cultural humility and worked hard to demonstrate cultural competence in treating the victims of the earthquake in Haiti, at the same time the *Comfort* staff was relentless in their attempts to salvage every life they could. When patients or the Haitian government were not initially in agreement with the treatment plan offered, the Comfort staff worked harder to make them understand the benefits and the alternatives to the recommendations. For example, there were two burn victims, one of whom was at a gas station which had a massive explosion at the time of the earthquake, in need of treatment in a tertiary burn unit. These burn victims were evaluated by two intensivists who determined that the *Comfort* did not have adequate resources to care for these two patients and they could have good outcomes if they were immediately medically evacuated to the United States (Etienne et al., 2010). After careful consideration, the MSPP consented to having the burn victims medically evacuated to the United States and arrangements were made for the transfer to burn centers in the US. There were many other patients, including children, with life threatening conditions who were transferred to the United States in similar fashion.

Psychological Trauma in Humanitarian Missions

The amputated limb is largely recognized as the signature wound of the earthquake in Haiti partly because of the obvious disability that comes with such an injury. The latest statistics from the earthquake state that there were over 250,000 killed and over 300,000 injured (Booth & Sheridan, 2010). In addition to the many people who have suffered head trauma leaving them in comas, the people with spine fractures which have left them paralyzed, and those with ischemic or infected limbs who have required amputations were a group of patients whose wounds were not so obvious. Those patients were often the ones who were fortunate enough to not suffer severe physical trauma at the time of the earthquake. Some may have suffered from a mild traumatic brain injury or concussion and appeared to have fully recovered. Those patients while they retained their limbs and had recovered consciousness, they had suffered different losses; they suffered the loss of their family members, friends and resources. These patients are suffering from the silent wounds of psychological trauma and because they often lack obvious physical wounds, it can be quite difficult for them to get care at many of the acute care facilities throughout Haiti. The silent wounds of psychological trauma are wounds that medical providers participating in humanitarian assistance and disaster relief missions are increasingly recognizing and should be trained to recognize. As the *Comfort* staff visited facilities ashore, more patients with purely psychological trauma were seen. An illustrative example follows:

Case Presentation

NB was a 10 year old boy who was hit by a block in the left frontal area of his head during the earthquake. It was not clear whether or not he had associated loss of consciousness. Since the earthquake he had been having headaches in the left frontal area of his head. He was also having nightmares on a nightly basis and he was startled/distressed when he heard loud sounds. He regularly had flashbacks and he often felt as if an earthquake was coming. He also reported having trouble sleeping. He had a history of syncope before the earthquake which worsened after the earthquake. He presented to one of the facilities ashore that the *Comfort* staff visited later in the mission. He had a normal mental status examination and the remainder of his neurological examination was non-focal. He did have a superficial laceration in the left frontal area of his scalp but no other evidence of trauma. Despite his normal examination, he expressed a fear of entering buildings because he thought they would collapse from an earthquake (aftershock). Given the history of increased syncope episodes, he had an EKG done which was reportedly "irregular" and he had an Echocardiogram performed by a cardiologist from USNS *Comfort* which was documented as "normal." He was diagnosed with Post Traumatic Stress Disorder. He was treated for his headaches and referred for further psychological intervention on the island.

Ordinarily part of the psychological counseling would have included reassuring the young boy by saying it is alright to go into buildings, but given the high frequency of earthquake aftershocks with significant movement magnitude which were claiming the lives of many Haitians, those comforting words could not be provided to this young man. After having seen so many of their loved ones crushed and killed in their own homes, families in and around Port-au-Prince feared returning to their homes. The Haitian government issued warnings locally that families should not return to their homes for fear that they may collapse. Even the national Palace, which is now slated to be demolished, was considered

Figure 6. Haitian Palace in Nov 2010. Taken by Dr. Mill Etienne.

unsafe for occupation by the President of Haiti. Families with means built small shelters behind their houses where they stayed for months after the earthquake. These shelters were considered safer because there would be less risk for injury if they were to collapse from an earthquake aftershock (Figures 6 and 7).

Many of these patients like NB did not make it onto the *Comfort* unless they had other obvious physical wounds. For example, on the *Comfort* there was a 30 year old nursing student who presented with right hemiparesis and an inability to walk. On examination she had a normal mental status, normal language function, and normal cranial nerve examination. She had right hemiparesis which did not follow a neuroanatomic pattern of weakness. She had no history of physical trauma and had no evidence of physical trauma on examination. Head CT was normal and imaging of her cervical and thoracic spine was also normal. Although an MRI of her brain and cervical spine would have provided more information, this was not available to the staff in Haiti. Her evaluation was most consistent with conversion disorder. She received psychiatric evaluation and was discharged with a recommendation to get further psychiatric intervention. As part of her discharge summary, recommendation of getting an MRI of her brain and C-spine if they should become available was also made.

Although the staff on the USNS *Comfort* worked very hard to save as many lives as possible, there were numerous deaths on the *Comfort* that were unavoidable. Many of the patients who died on the *Comfort* were young children, like the baby with tetanus who died soon after arrival on the *Comfort*. Seeing a young child die is difficult for anyone, but having to tell a parent that their child has died is news that nobody ever wants to bear. The staff on the USNS *Comfort* had to do that multiple times throughout the mission. As difficult as it was for the staff to deliver the news, it certainly would not compare to the feelings

Figure 7. House built as temporary lodging so families do not have to stay in their main house which may collapse with aftershock. Photo taken by Dr. Mill Etienne.

the parents experienced from receiving the news. These parents too were experiencing psychological trauma which would need to be addressed. The story of one patient follows:

Case Presentation

ML was a 58 year old woman without significant past medical problems who was in a house that collapsed at the time of the earthquake. She was found unresponsive. After waking up she did not appear to have any physical trauma and so was not evaluated in a hospital. She was evaluated by a neurologist from the *Comfort* one month after the earthquake at a local clinic. She reported having nightmares and was "jumpy" during the night. She had worsened memory and she was amnestic for events surrounding the earthquake. She did not recall the earthquake and had to be repeatedly reminded that there was an earthquake. She stated that she can tell that something happened given that she saw destruction all around her. She was not aware that many of her family members and friends had died during the earthquake and at the time of the evaluation her family members felt she was still not ready to be given news of the death of many of her loved ones. She did not know who the President of Haiti was but recalled who she voted for during the last election. She also had diffuse body aches and hyperacusis.

Physical evaluation revealed displaced bone in second digit of her left hand and she had bilateral frozen shoulders, however no evidence of head trauma. Given her limited physical findings, it would have been very difficult for this patient to receive medical attention in post-earthquake Haiti, and it would have been even more difficult to have her admitted to the USNS *Comfort* medical treatment facility. This patient had dissociative symptoms as may be seen with psychological trauma. Arrangement was made for her to be transferred to the *Comfort* where she received a basic workup which included a CT scan of her head which was normal and she had more detailed psychiatric evaluation. Although she did not stay on the *Comfort*, provision was made for her to receive further psychological evaluation and intervention. Her discharge diagnosis was Post Traumatic Stress Disorder (PTSD).

Prior research has shown that losses of personal, social, and material resources resulting from traumatic events significantly contribute to psychopathology (Hobfoll, 1989; Jacobs, 2007). This has been demonstrated after Hurricane Katrina (Zwiebach et al., 2010), after the terrorist attacks on the Twin Towers in 2001 (Hobfoll et al., 2006), and after other earthquakes around the world (Sattler et al., 2006; Sumer et al., 2005). This is based on the conservation of resources model which has been used to predict which survivors of disasters are at highest risk of experiencing psychological distress (Hobfoll, 1989). The model posits that individuals seek to acquire and maintain valued resources and the loss of those resources uniquely distresses the individual (Hobfoll, 1989).

Although the conservation of resources model has been demonstrated in numerous disaster settings, it has yet to be formally tested in post-earthquake Haiti. Nonetheless, one of the most important interventions for victims of psychological trauma is to connect them with appropriate community organizations that can offer support whether it be in the form of counseling or helping them find ways to recover or replace the many resources they have lost. Such measures are particularly difficult to put in place after a disaster but nonetheless should be a routine part of any HADR mission. As an example, during the relief effort the *Comfort* established a family reunification program called "The Care Line." This was in direct response to knowledge that many families were separated from each other at the time of the earthquake. The care line phone number was distributed using local Haitian media outlets as a number for families to call when they were looking for their loved ones. The "care line" was manned 12 hours a day by interpreters with additional hours for outgoing calls on demand. The "care line" was successful in reuniting numerous families, including 18 displaced children who were being cared for on the *Comfort*.

Disengagement

While the USNS *Comfort* could stay in Haiti for an additional decade and be kept busy doing very important work, they would no longer be engaged in a disaster relief mission but would rather be involved in a purely humanitarian mission. As the USNS *Comfort* departed Haiti, the USAID quickly became the most prominent representative of the United States government in Haiti. The USAID has continued to give humanitarian assistance to the people of Haiti and they were able to provide immediate assistance to Haiti during both the hurricane Tomas and the Cholera epidemic.

Just as there should be guidelines for engagement in HADR missions, there should also be guidance on the disengagement process. The hallmark of the natural disaster that makes it a public health emergency prompting international medical relief effort is the excess or indirect morbidity or mortality (Burkle, 2010). That is the morbidity and mortality occurring after the natural disaster exceeds what is typical for that country or region. In resource-poor communities, this excess morbidity and mortality typically overwhelms the local government and public health infrastructure. While the appropriate time for disengagement has been debated in many circles, those who have been involved with prior disaster relief missions offer the guidance that the appropriate time for disengagement is when the morbidity and mortality for the community receiving the aid has returned to the baseline for that locale. Those participating in the relief effort often find it rather difficult to disengage. This is partly due to the human virtues of empathy and compassion where the aid providers come to appreciate the suffering that the victims of a disaster are experiencing and so the act of leaving a people when there is still a great need for assistance may begin to create a feeling of cognitive dissonance in the aid providers.

The ease of disengagement may be different when providing aid to a developed country versus providing aid to a resource poor country. The resource poor country is typically depleted of what little resources they had and so it may take longer for them to return to the baseline for the community. In the case of Haiti, given that many of the hospitals and the limited public health infrastructure were destroyed, they have yet to return to the baseline morbidity and mortality for the country. For example, only months after the immediate disaster relief ended, the citizens of Haiti were threatened with a hurricane and were gripped by a deadly cholera epidemic. As of 17 December 2011a total of 121,518 cases of cholera were documented in Haiti, resulting in 63,711 hospitalizations and 2,591 deaths (MMWR, Dec 2010).

Those who have stayed in Haiti far beyond the immediate earthquake relief and those who continue to travel to Haiti understand that the recovery from this disaster will take years and possibly decades. The devastation in Haiti provides volunteers an opportunity to save lives and to improve the quality of life of the Haitian people. To that end, local physicians and nurses who were receiving the many patients being discharged from the *Comfort* and nurses were invited onto the ship to get specialized training so that they could better be able to treat the complex patients they would be receiving. Training included airway management, wound care, physical and occupational therapy among many other skills that would help to improve the quality of life of the patients who were being discharged from the USNS *Comfort*. The training and supplies provided to the local healthcare providers was a way of providing the local people with additional resources and so this served to ease the disengagement process.

Many fields of medicine (Gilliam, 2002; Wyrwich et al., 2010; Lee et al., 2010; Gerhards et al., 2010; Jokinen et al., 2010; Francesschini et al., 2010; Smith et al., 2010) utilize health related quality of life as a measure of disease outcome because of the realization that both quantity of life and quality of life are important to the patient. The patient-

oriented outcome assessment serves to bridge the science and the humanities in the delivery of healthcare. For the same reasons, humanitarian missions should consider utilizing health related quality of life as one of the measures of the success of their interventions (Figure 8).

Figure 8. Physicians and nurses from Haiti who came aboard the *Comfort* to get specialized training. Left to right: Dr. Torrilus, Nurse Evelyn Paul, LCDR Etienne, LT Thomas, Nurse Wilda Maejnant, Doctor Pierre Andre Balde.

Conclusion

The earthquake in Haiti, like other international disasters, provided an opportunity for people around the world to offer humanitarian assistance. When offering humanitarian assistance the concepts of race, nationality, religious belief, class, creed, and gender quickly lose relevance. What becomes relevant is the drive to save lives and eliminate human suffering which takes precedence over all natural and man-made barriers between human beings. The medical student, the nurse, the social worker, the physician, the physical therapist, the chaplain and anyone else who has ever made a sacrifice to help someone else has experienced humanism. By respecting the sovereignty of the host nation (Haiti) and by respecting the cultures, customs and traditions of the local community the practitioners on the USNS *Comfort* have set the standard for how to offer HADR. Although the Rockefeller commission found that humanities itself may not give the answer of what it means to be human, the combination of healthcare, science and humanities does provide the opportunity for one to get a better understanding of what it means to be human.

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Global Snapshots of Treatment Abandonment in Children and Adolescents with Cancer: Social Factors, Implications and Priorities

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Abstract

Treatment abandonment (i.e., failure to start or complete curative treatment) by patients with cancer has global implications at the individual and societal levels. In resource-limited settings, it is a frequent and significant contributor to poor outcomes; in resource-rich settings, the rare instances of abandonment are associated with prominent media scrutiny and legal ramifications. In this article, diverse social factors that may mediate abandonment in children and adolescents are explored as we discuss worldwide cases from individual and

systemic perspectives. We highlight individual patient scenarios from the literature and media of resource-rich settings, and aggregate experiences of the many more patients affected in resource-constrained areas. Context-specific legal and ethical considerations are discussed. Next, we describe implications of abandonment across the globe, particularly those for patients, families, and providers. Finally, we provide an overview of strategic priorities to address abandonment systemically. Understanding and working together to address the social factors and implications of abandonment are vital to improving the global care of children and adolescents with cancer, particularly where the need is greatest.

Keywords: abandonment, pediatric oncology, childhood cancer, adolescent, treatment refusal, world health

Introduction

The failure to start or complete curative treatment by cancer patients, known as treatment abandonment, affects individuals and communities in both resource-limited and resource-rich settings. The social factors and implications associated with treatment abandonment globally are broad, and additional resources and attention are warranted to address the roots of these issues. Here, we present two fictional cases adapted from scenarios in the literature and ones we have encountered. We hope to encourage the reader to ask: Why does treatment abandonment occur, and why does it matter? What can be done about it?

Case Scenario One: Patricia

On arrival to the Oncology ward, Patricia's eyes showed obvious pain as her bruised belly rose with each heavy breath. Speechless with worry, her mother wondered how her lively 5-year-old's illness that seemingly started just a few days ago had turned into this.

Doctors explained that Patricia had Acute Lymphoblastic Leukemia (ALL), meaning "blood cancer;" after she was stabilized, treatment—provided for free—would include chemotherapy and day clinic visits, typically several times a month, for more than two years. During the next month, as Patricia received rounds of antibiotics, chemotherapy, and various tests, her mother grew familiar with the ward routines, team visits, hygiene precautions, and steps needed to look after her daughter. Relieved that Patricia was better, her mother never expressed doubts about the treatment plan. When asked whether she was aware how near death Patricia had been and how important it was to follow the treatment plan, she always answered, "yes."

It was a different child with sparkling eyes who left the ward to go home to her family in a small province, one hour away according to the map. But Patricia did not come back for her appointment the next week, nor even the next month.

Ten months later, Patricia and her mother returned. Just as before, her condition was deplorable, with bleeding and vomiting. Her smile was gone; her eyes were again unlit.

Tireless efforts were initiated in the small Intensive Care unit, with the team fighting to make resources available. Her mother was, again, speechless. Because Patricia had not completed treatment, doctors thought she could still benefit from starting protocol

treatment and possibly be cured if she survived this crisis and actually received all of her treatments this time.

Patricia did again recover. Multiple plans were set before her discharge; her mother would have help from her sister to return, and they would move to her sister's house in a nearby small town with better transportation. But Patricia never returned. Months later, the team heard back from the local village that Patricia had died at home a few months earlier.

Case Scenario Two: Josiah

When he was first brought to his pediatrician's office, Josiah seemed just a bit more pale and tired than usual. His parents could scarcely believe that the blood work, which was done "just to be sure," had shown their lively 5-year-old to have ALL. As they were quickly admitted to the area's Pediatric Oncology ward and guided through a series of tests, his parents were relieved to learn his was standard-risk disease, with more than 80% chance of long-term survival. They learned from their multidisciplinary team all about the treatment plan, including chemotherapy drugs, potential complications, and regular day clinic visits for the next two-and-a-half years.

Josiah tolerated his chemotherapy well and was ready in two weeks to return home, an hour away. When his parents had trouble with Josiah's central line that was placed to facilitate ongoing chemotherapy, they promptly brought him in, and the trouble was resolved. The family returned for follow-up regularly, and the bone marrow results at the end of the month showed the desired response: Josiah's leukemia was in remission.

When Josiah did not return the following week to have his blood work checked and start his next chemotherapy course, his contact nurse and social worker called his parents and left messages. His parents called back to announce that they had researched alternative treatments with high doses of vitamins and herbal combinations that were effective in re-setting the immune system. They had heard stories from others and online about how exceedingly sick children get from chemotherapy, not to mention the long-term side effects. They felt confident that because Josiah had always been healthy, he would best be cared for exclusively with alternative treatments that others praised online. When the family declined to return with Josiah, the hospital team informed them that Child Protective Services (CPS) had to be notified, with the intention being to ensure that Josiah's best interests were maintained.

Media surrounded the urgently called court case later that week. The judge ordered that Josiah's parents did not have the constitutional right to refuse life-saving treatment for Josiah and placed him under the temporary custody of CPS. His parents continued to appeal as media debates raged over the rights of parents and health providers or government to decide on a child's course of treatment.

Background and Rationale

Although the cases of Patricia and Josiah both illustrate abandonment of cancer treatment, their stories are rooted in very different contexts. Childhood cancer affects an estimated 250,000 children globally each year, with excellent survival rates of approximately 80% for those presenting in resource-sufficient countries such as Josiah's (Kellie & Howard,

2008). Unfortunately, approximately 80% of childhood cancer cases occur in resource-limited settings similar to Patricia's, where significant diagnostic and management challenges are associated with far inferior survival rates (Burton, 2009).

Abandonment of treatment, defined as the failure to start or complete treatment intended to cure, has been postulated to be a factor in as many as 60% of childhood cancer cases in resource-limited areas, and to be a major contributor to significantly reduced survival in these settings (Mostert et al., 2011). Both in the literature and in practice, abandonment has been inconsistently documented and may be known as "defaulting," "absconding," "running away," "dropping out," or going "HAMA" ("home against medical advice"), and variably related to treatment refusal. The very same systemic processes that may increase the likelihood of abandonment, together with how common abandonment often is in resource-limited settings, often makes abandonment challenging to measure. To maximize capture and understanding of this phenomenon, Mostert's (2011) definition of abandonment on behalf of the International Society of Pediatric Oncology's Abandonment of Treatment Working Group thus encompasses refusal of curative treatment both from the outset and after starting treatment.

Although abandonment is far less common in resource-rich countries, the media as well as the literature from higher-income countries do discuss these rare cases and the dilemmas they pose with interest (Alessandri, 2011; Laengler et al., 2011; Hord et al., 2006; Ridgway, 2004) (Talati et al., 2010; Kent et al., 2011). The potential implications of abandonment in resource-rich settings may be severe (Alessandri, 2011; Hord et al., 2006), especially on an individual and at times broader social level; as we present below, impact can range from criminal convictions to significant deteriorations in patients' health from treatment delays.

We propose that performing a selected global overview of abandonment cases according to this recent definition of abandonment will enable us to appraise cross-cultural issues from fresh perspectives. To better recognize the vast and often undocumented burden of abandonment in resource-limited settings or lower-income countries (LICs), we will discuss individual cases from higher-income countries (HICs) in which such details are more typically available, together with summative data from patients in LICs. Given that readers in HICs often become morally indignant at the perceived injustices raised in the exceedingly rare stories of abandonment in HICs, we wonder whether the indignation that we feel about these stories will help us to better mount an appropriate outcry for the millions of children who must abandon their chance for cure in LICs.

The disparate access to cancer control and resultant survival rates across the globe stand as a critical call for social response. Rather than diminish public health efforts in resource-limited settings, efforts to improve cancer management serve to strengthen the health system as a whole (Farmer et al., 2010). As the World Health Organization's 2008 World Cancer Declaration pledges for "major improvements in cancer survival rates in all countries" by 2020 (Coleman, 2011), the reality remains that such changes are only possible with integrated global and local efforts. We believe that decreasing abandonment is key to reducing cancer disparities, and hope this article raises the interest and readiness of readers to respond to the global imperative to reduce abandonment of cancer treatment.

Caveats

Abandonment should not be viewed as a sign that the families involved are not resilient or have committed personal wrongs. The reasons for abandonment are complex, diverse, and often deeply rooted socially. We hope to suspend biases to examine abandonment's many facets, not impose negative judgment on the families involved.

We recognize that complementary and alternative medicines (CAM) have great value as supportive therapies for many children with cancer (Bishop et al., 2010) by reducing symptoms such as nausea. However, no peer-reviewed medical literature exists stating that CAM can cure cancer on its own; thus, patients who exclusively seek CAM are considered to have abandoned curative treatment.

The vital discussions concerning "right to die" or end-of-life decisions will not be our focus here. Although readers should be aware that public commentaries may blur the issues (e.g. equating cancer with end of life), we believe these are distinct discussions. Here, we will specifically discuss abandonment or the refusal of curative therapy in the context of at least one party having recognized the reasonable possibility of cure. This is not an exhaustive look at abandonment; however, by highlighting areas of interest, we hope to spark discussions, research, and innovative solutions to collectively address abandonment and improve the care of children and adolescents with cancer worldwide.

Cross-Cultural Cases

Snapshots from HIC: Selected Cases

Records of children with cancer in HIC taken to court over issues of treatment abandonment exist from as early as 1933 (Ridgway, 2004). By using PubMed, Google, and a snowball effect (i.e., secondary cases identified from those initially found), 27 cases were identified, of which 10 have been highlighted in Table 1. Table 2 summarizes all 27 cases' key demographic data as well as key reasons and implications associated with abandonment. References for these 27 cases are shown in an end note at the conclusion of this article. Data from informal sources (e.g., blogs) that could not be verified in reviewed publications, established news sources, and court transcripts have been excluded because of the polarized writing that often characterizes discussions on this topic. We acknowledge the publication bias, as the cases with sufficient detail included are largely those taken to court; media coverage of even fatal cases of treatment refusal are historically known to be incomplete (Asser, 1998), and there certainly are less "dramatic" cases of abandonment in HIC that have not been documented (Tables 1 and 2).

We did not apply the operational inclusion of a four-week time interval in which a patient fails to follow-up (Mostert et al., 2011; Bonilla et al., 2009; Sitaresmi et al., 2010) as part of our case selection criteria in HIC. There were many cases in which the intent to abandon curative treatment was explicit and implied to be ongoing, even if active legal or social intervention resulted in new care decisions being re-established before a strict four-week hiatus. It seems likely as more cases of abandonment are explored globally that its operational definition may evolve.

Table 1. Selected Cases of Abandonment in Pediatric Cancer in High- or Upper-Middle-Income Settings

Case Setting	Patient Demographics* & Reported Survival Chance if Standard Rx (%)	Reasons Cited for Refusal/ Abandonment	Reactions to Refusal/ Abandonment & Initial Legal Outcomes	Patient/Family Clinical & Final Legal Outcomes**
Minnesota, US, 2009 (Associated Press, 2009; USA Today, 2009; Jones and Pesce, 2009; CNN, 2009; Fox, 2010; NYT, 2009)	- 13 y, M - Hodgkin lymphoma - 90% (5% if no Rx)	- Religion, including role as "medicine man" in faith group - CAM, SE - Saw illness as not serious	- Court ruled "medical neglect" and need for CPS	- Left state against Court orders; warrant for arrest issued - Returned and agreed to Rx - Completed Rx. Well at 14 y, in remission
Massachusetts, US, 2009 (ABC, 2008; CBS, 2011)	- 8 y, M - Non-Hodgkin lymphoma (2007); autism - 92%, 10% after abandonment	- Concerned over SE	- CPS involved and patient taken to live with father	- Cancer re-presented as leukemia in 2008 - Died in 2009 - Mother convicted of attempted murder and abuse
Washington, US, 2007 (Ross, 2009; Black, 2007)	- 14 y, M - ALL - Jehovah's Witness - 70%	- Refused transfusion needed to sustain life after start of chemo	- Parents sought help of CPS to counter refusal; hospital supported patient's right to refuse as mature minor	- Court granted refusal with patient as mature minor - Died less than 12 hours after court order allowing refusal of transfusion
Virginia, US, 2005 (Ross, 2009; Mercurio, 2007; Moore, Markon, redorbit, Caplan)	- 15 y, M - Hodgkin lymphoma	- Refused Rx due SE - Prayer and CAM	- Parents charged with neglect - Charged to continue Rx	- Order for Rx overturned; CAM and RT given instead with no chemo. - Cancer recurred several times. - Well at 18; delays in school - Resulted in state law allowing refusal of standard Rx (see text)
Saskatchewan, Canada, 1999 (Toronto Star, 1999)	- 13 y, M - Osteosarcoma - Fundamentalist Christians - 65%, (10% after second refusal)	- Refused chemo and amputation upfront and again refused after 2 rounds of court-enforced chemo - CAM in Mexico - Prayer	- Court ruled twice for province to make medical decisions for patient; patient ruled not competent to make own medical decisions	- After second ruling, CPS dropped case after lung metastases shown in court-ordered check-up - Family went to Mexico for CAM; died 70 days after return from clinic
Vienna, Austria, 1995 (Lancet,1996)	- 6 y, F - Wilms Tumor - from 90% to 10% after delay	- Refused chemo and surgery, on advice of a "quack healer" in Germany whose medical license had been revoked for unorthodox views (cancer as "state of mind")	- Fled to Spain to avoid Court-ordered treatment. - Much media involvement and commentary, including from national leaders; parents' supporters staged hunger strike	- "Tiny" tumor grew to 4 kg by the time Court took custody and ordered chemo - Patient in remission 1 year later - Parents charged with inflicting grievous bodily harm: given 8-month suspended sentence - Healer charged with neglect/ torture

continued

Case Setting	Patient Demographics* & Reported Survival Chance if Standard Rx (%)	Reasons Cited for Refusal/ Abandonment	Reactions to Refusal/ Abandonment & Initial Legal Outcomes	Patient/Family Clinical & Final Legal Outcomes**
Perth, Australia 2009 (Spencer and O'Leary, 2009, Alessandri, 2011)	- 10 y, F - Embryonal hepatoblastoma; - Father anesthetic technician, originally from Zimbabwe; mother from Central America - 30%	- Natural therapy (clay wraps) in Perth, continued in El Salvador (grandmother provided CAM in local community) - previous success with natural therapy for asthma and eczema - Faith in God for healing	- Left for El Salvador before Court date - General practitioner familiar with family's culture and language involved to help; hospital Ethics Service declined by family; CPS aware but no apprehension	- Since patient had left the country, no ruling was made due to futility and to minimize risk this would lessen patient's chance of returning - Family pursued chemotherapy in Central America hospital when patient deteriorated; she died in El Salvador ~ 3 months after diagnosis
Hong Kong (Hui, 2008)	- 17 y, M - Osteosarcoma - 80-90% cure with Rx including immediate amputation	- Refused all Rx upfront - Father took patient to Mainland China for CAM, concerned over amputation and chemo effects	- Medical team decided not to seek CPS Court protection to preserve relationship with family and openness to return when CAM failed	- Agreed to chemo and amputation after 3 months when pain and mass grew - Family continued to cooperate with care over next year even when patient had significant treatment-related side effects, and lung metastases found and recurred
Hong Kong (Hui, 2008)	- 15 y, M - Primitive neuroectodermal tumor (PNET) - 70% cure with Rx including amputation	- Refused all treatment upfront and continued to refuse amputation to end - Father sought CAM by "medical practitioner" (herbalist) in Taiwan	- Contact lost with family for 4 months	- Family returned after 4 months when CAM failed; mass had doubled in size - Responded well to palliative RT and chemo; offered amputation with 30% chance again for cure. Again refused - CAM continued; poor pain control - Died after acute bleeding from mass
Chile (Mcnab and Beca, 2010)	- 11 y, M - relapsed ALL (2 years after initial) - 50%	- Bad experience with SE from previous chemo - Perceived low chance of cure, other friends had died - Wanted CAM	- Doctors took legal action - Court initially determined in favor of doctors	- Court reversed decision and ruled not to force standard Rx because of its "high human costs" and little guarantee of success - Child died 7 months after ruling

ALL = Acute Lymphoblastic Leukemia; AML = Acute Myeloid Leukemia; CAM = Complementary and alternative medicine; chemo = chemotherapy; CPS = Child protective services; IV = intravenous; RT = Radiation therapy; Rx = Treatment; SE = Side effects.

*y = years of age at time of initial abandonment; M/F = male/female.

**Only confirmed/publically reported details regarding remaining alive or otherwise included—as of last available updates.

Snapshots from HIC: Aggregate Data

The general population's incidence of abandonment in resource-rich settings has not been established. Recently, Laengler et al. (2011) characterized the abandonment experience of 70 (of 73) pediatric oncology clinics in Germany over two years and found an annual incidence of 0.5%, an expectedly low rate in such a resource-sufficient setting. Most of those who had abandoned treatment did so after starting it and then quitting largely because of parental personal beliefs and coping.

Snapshots from LIC: Aggregate Data

In a resource-limited setting where cure may not be possible and exclusive palliative treatment may be more appropriate, determinations of what constitutes abandonment can be additionally difficult. These difficulties are compounded by the scarcity of resources needed to prevent or manage abandonment. Thus, the existence of gaps in abandonment monitoring in such settings is unsurprising.

Associated Social Factors in LIC

As many as 90% of the estimated 10,000 children and adolescents younger than 18 years who are affected by ALL in China have been estimated to not start or complete treatment, largely due to inadequate finances; adapted protocols in this setting may be up to $25,000 USD per patient (Gu et al., 2008). Financial challenges are well documented throughout resource-limited settings. The experience of one center in Nigeria found that 52% of children with Burkitt lymphoma abandoned a 12-week course of therapy, primarily due to inability to afford treatment; the total cost of complete treatment for a typical child in that setting was less than $165 USD (including approximately 60% direct chemotherapy costs), which was still nearly four times the local state employees' monthly starting salaries (Meremikwu et al., 2005).

However, abandonment is clearly multi-factorial in nature. The results of a study in Indonesia following up with families who abandoned ALL treatment showed that, although 60% noted financial challenges as being part of

Table 2. Summary of Selected Cases of Abandonment in Pediatric Cancer in High- or Upper-Middle-Income Settings

Age (n=27)	11.2 (8 mo to 17 y)
Gender (n=27)	21 Male; 6 Female
Diagnoses (n=27)	
Lymphoma	6
ALL	6
AML	5
Osteosarcoma	4
Ewing Sarcoma	2
Other	4
Baseline Prognosis ¥ (n=18)	
> Above 80%	7
> 40- 80%	7
> Below 40%	4
Care Refused *	
Chemotherapy	24
Follow-up / Work-up	11
Surgery	7
Transfusion	7
Named Reasons *	
CAM	16
Religion	14
Side Effects	9
Trust	2
Reported Social Impact *	
CPS involved	14
Left town	11
Custody affected	11
Arrests / Warrants for Arrest	7
Court Decisions (n=25^)	
Court-ordered Rx	17, of which 9 reversed
Court-allowed Refusal	5
Court-allowed Non-Standard Rx	3
Last Reported Outcome	
Died	13
Alive	5
Unknown	9, including 3 relapsed

¥ Probability for cure and long-term survival as predicted for specific case.

* May involve more than 1 item for each case.

^ 2 cases did not involve the Court.

their reason for abandonment, only 16 % identified it as the sole reason. Furthermore, just as many families (60%) reported their perception of ALL as incurable as being a key reason (Sitaresmi et al., 2010). A follow-up study of ALL patients who abandoned treatment in China found a similar proportion of patients (over two-thirds) whose primary reason for abandonment involved the perceived incurability of ALL (Wang et al., 2011).

In addition to challenges with finances and perceptions of disease incurability, social risk factors reported with abandonment across different countries (noted as a non-comprehensive sample for illustrative purposes) have included:

a) Familial factors such as larger household size (in El Salvador: Bonilla et al., 2009), understanding of child cancer concepts (in Indonesia: Mostert et al., 2010) limited literacy (in India: Kulkarni et al., 2009; in El Salvador: Bonilla et al., 2009), and discordance between parents (in China: Wang et al., 2011).

b) Societal factors such as socio-political instability leading to drug shortages (in Iraq: Frangoul et al., 2008).

c) Negative experiences, including significant side effects (including pain) or bad experiences with health care providers, which may include issues with trust, lack of skill, or poor communication (in Indonesia: Sitaresmi et al., 2010; in India: Seth, 2010; in various: Arora et al., 2010).

d) Perceptions about treatment, such as inadequate faith in treatment effectiveness or necessity; fear of chemotherapy and/or preference for traditional medicine; fear of treatment-related adverse effects (in Tanzania: Krüger, 2005; in India: Kulkarni et al., 2009; in China: Gu et al., 2008, Wang et al., 2011).

e) Logistic issues, such as ward space availability and transportation issues (in Indonesia: Sitaresmi et al., 2010; in China: Wang et al., 2011). Studies in different contexts have reported differences in whether travel distance to treatment centers was significantly associated with the risk of abandonment (in Honduras: Metzger et al., 2003; in El Salvador: Bonilla et al., 2009; in China: Wang et al., 2011).

Socio-cultural values may also be reflected in a potential gender disparity, with higher abandonment rates in females (in addition to potentially reduced presentation to medical attention) in some, but not all, cases (Moleti et al., 2011) (Wang et al., 2011) (Arora et al., 2010).

Associated Clinical Factors in LIC

Having a favorable type of cancer with excellent prognosis in HIC, such as Wilms tumor with over 90% overall 5-year survival, is not sufficient to protect patients from abandonment in LIC, as was demonstrated in Sudan, where more than 50% abandoned (Abuidris et al., 2008), and in Malawi where 85% abandoned (Wilde et al., 2010).

Abandonment has been found to occur particularly near the start of therapy (Metzger et al., 2003; Gu et al., 2008; Luo et al., 2009; Sitaresmi et al., 2010; Wang et al., 2011), as well as later in the course of treatment (Krüger, 2005; Moleti et al., 2011). This

variability may be related to the duration of treatment for different cancers, as well as the visibly rapid response of some cancers to chemotherapy, such as endemic Burkitt lymphoma. Patients with endemic Burkitt lymphoma have been shown to abandon treatment after either good or poor responses (Krüger, 2005; Meremikwu et al., 2005), presumably related to perceptions of treatment necessity or futility.

A patient's overall health may also be associated with abandonment. A recent study by a Central American group (AHOPCA) studying nearly 1800 children with cancer (Sala et al., 2011) found severe malnutrition at diagnosis to be associated with increased risk for abandonment and worse outcomes; however, severe malnutrition typically also reflects socio-demographic variables. Altogether, disease factors such as diagnosis, length of treatment, risk group, or health status have not been independently associated with abandonment (Arora et al., 2010).

Strategies to Address Abandonment in LIC

Strategies required to address abandonment appear to be highly context-dependent. One center in Tanzania reported 100% abandonment despite having fairly adequate facilities, supportive care, and adapted protocol-based efforts for Burkitt lymphoma that requires relatively short courses of chemotherapy (Krüger, 2005). This supports the premise that abandonment is a function of diverse social risk factors, as mentioned above. In the setting of available public health insurance in Shanghai, China using adapted protocols, abandonment was 20.6% (Gu et al., 2008). Attempts to address abandonment by only considering more visible factors such as economics or material resources may miss addressing the holistic issues involved; as one illustration, in Indonesia, programs that integrated patient education in addition to those with a primarily economic focus resulted in greater impact on abandonment (Mostert et al., 2009; Mostert et al., 2010).

The formation of a cooperative group (French-African Pediatric Oncology Group) dedicated to promoting outcomes in several African countries, including Malawi, poses an example of how regional and global partnerships progressively adapted local Burkitt lymphoma treatment protocols to reduce treatment toxicity, duration, drug-related costs (reduced to less than $50 USD), and tolerability. In Malawi, these efforts improved survival rates and reduced abandonment rates from an estimated 75% to less than 3% (Traoré et al., 2011; Hesseling et al., 2008; Hesseling et al., 2005; van Hasselt et al., 1995). Similarly, for Hodgkin lymphoma patients in Morocco, use of a national adapted protocol and provision of social as well as financial assistance were associated with abandonment reduction from 50% to 9% (Hessissen et al., 2010).

In Latin America, several multi-modality programs have also exerted considerable efforts to reducing abandonment. In El Salvador, where existing systems to reduce abandonment include social worker house visits, free treatment, and free lodging and childcare for those far remote areas through international and local support, abandonment has been noted at 13% (Bonilla et al., 2009). In Guatemala, the establishment of a dedicated multidisciplinary pediatric hematology oncology unit was associated with a significant decline in abandonment from 42% to 12% (Luna-Fineman et al., 2002).

In Recife, Brazil, a twinning partnership with St. Jude Children's Research Hospital helped cultivate multi-faceted programmatic improvements between 1980 and 2002. During this time, the development of a pediatric hematology oncology unit that incorporated the provision of transportation, lodging, and food for patients significantly reduced abandonment; concurrent with an almost two-fold increase in 5-year event-free survival, abandonment-related treatment failure dropped from 16% to 0.5%, (Howard et al., 2004)—matching the abandonment rate seen in Germany (Laengler et al., 2011).

Social Factors

Considering the case scenarios, summative reports, and empirical and anecdotal data, we used two ways to illustrate some simplified considerations that may typically bear different weight in LIC and HIC settings. First, we created two different word clouds (with publicly accessible software, wordle.net), where pasted text is represented in different sizes depending on frequency of occurrence. For HIC (Figure 1), this was derived from

Figure 1. Abandonment factors and implications in high- and upper-middle-income countries (case-derived).

keywords created from the 27 cases identified, while for LIC (Figure 2), this was a theoretical creation based on gestalt impressions from experience and the literature, including studies on abandonment in Asia, Central and South America, and Africa as summarized in other reviews (Arora et al., 2007) and in specific studies cited above (Figures 1 and 2).

Figure 2. Abandonment factors and implications in low- and lower-middle-income countries (theoretical).

Secondly, we represented potential differing social factors according to HIC and LIC settings (Figure 3); despite many sharp differences, we note that many factors, including perceptions of disease or treatment, may likely be important in both settings, even if they may not have the same manifestation or impact in HIC compared to LIC. For instance, even

Likely Greater Role in HIC	Likely Similarly Important in Both HIC/LIC	Likely Greater Role in LIC
Personal	**Personal**	**Personal**
Access to online resources	Health beliefs	Finances / Socioeconomic status
Perception of clinical trials	Influence of religion / personal faith	Patient gender
Access to high-profile CAM	Perception of CAM	Patient age
	Perception of standard treatment (including side effects)	Patient birth order and household size
	Education level	Opportunity costs of treatment
	Treatment toxicity or morbidity	Patient's actual prognosis
	Negative experiences	Nutritional status
	Perception of personal risk / health status	
Systemic	**Systemic**	**Systemic**
Legal governance	Symptom management (e.g. pain)	Access to transportation
Child protection services	Dynamics and power relations within family	Access to nearby lodging
Social rights relating to child health decision-making	Dynamics and power relations between health care provider and family	Access to standard curative treatment
Involvement of media	Trust and rapport with health care team	Access and eligibility for surgeries with less functional impairment (e.g. limb-sparing)
	Agreement within family/among decision-makers	Access to timely diagnostics
	Agreement among health care providers	Access to supportive care (e.g. blood products)
	Social acceptability of abandonment	Access to referral centers (e.g. for second opinions)
	Health communication in the media	Access to salvage therapy (e.g. radiation)
		Access to effective palliative care
		Access to familiar CAM practices
		Quality of public health infrastructure
		Local prognosis
		Social perceptions of cancer
		Social perceptions of standard treatment vs CAM
		Safety (physical/political/social) of treatment area
		Access to social capital (fundraising/donations)
		Access to psychosocial support (social work; counseling)
		Community influence in decision-making

Figure 3. Proposed differences in selected social factors affecting abandonment across higher- and lower-income settings.

though families in both HIC and LIC may want to minimize harm to their children and are concerned about treatment toxicity and morbidity, children in LIC are often exposed to far great toxicity and morbidity with less compensatory strategies at their disposal. In certain diseases such as cancers of the eye and bone tumors of the limbs for example, late presentations in LIC frequently lead to much more progressive disease (at times compounded by lack of access to expert care or other modalities of treatment), which leads patients in LIC to be offered much more extensive surgery to achieve potential cure, such as removal of the eye or amputation (in lieu of limb-salvage), with far less access to post-surgical support to maximize function. Thus, families may reject such morbid procedures due to concerns of bodily disfigurement, associated suffering, loss of function, and social stigma (Figure 3).

Other systemic and personal social factors that warrant mention as part of this holistic view include:

Perception of Personal Risk/Health Status

Differing perceptions in both HIC and LIC may contribute to patients' abandonment, including perceptions ranging from lack of risk (disease seen as not being serious) to lack of hope (childhood cancer seen as uniformly fatal and treatment futile).

An Hour Here Is Not an Hour There

Although both Patricia and Josiah may have lived an hour away from the hospital, there are typically vastly different implications for LIC vs. HIC settings. Transportation problems that may exist in HIC are typically significantly compounded in LIC. In LIC, an hour away on a map for those with resources for private travel may be very different for those requiring public transportation – and in some settings that may involve at least five bus transfers (Sitaresmi et al., 2010), mountainous terrain, or four-footed animal transport. In addition to considering access to public transportation and its frequency of operation and costs, there are also factors such as the safety of a treatment center and routes leading to it, whether politically, physically, or socially. Safety in various LIC can be a genuine concern in the setting of dissent among mixed ethnic or religious groups, where an hour-long journey becomes impossible due to armed roadblocks.

Public Health Infrastructure

In line with transportation issues, public health systems for hygiene and sanitation are important both in the hospital and home settings to minimize ongoing infection risks; this also includes consideration of whether there exists social support to promote uptake of essential childhood vaccinations, or to minimize rates of severe protein-calorie malnutrition that impairs immune response and health resilience. On the other hand, once cancer is diagnosed, the availability of chemotherapy and antibiotics, as well as other infrastructure and public health resources, is often essential to the process and efficacy of treatment as well as how it is perceived and received by the public.

Opportunity Costs and Less Visible Burdens

Beyond the explicit costs of hospitalization and treatment, the opportunity costs for family members to look after patients with cancer can be tremendous, both in HIC and even more so in LIC, where families have fewer reserves. On the surface, this ranges from

disturbance of childcare routines where others at home may be minors, or the inability to attend school and milestone events, to significant disruptions of social relationships and the inability to work and sustain vital family income.

Social Acceptability of Abandonment

The greater social acceptability of abandonment in some LIC settings may make it easier for some families to make this decision within an understanding community, while the rarity and lack of social acceptability in typical HIC contexts may make it an equally important deterrent to abandon in HIC. Since this is a part of the pervasive culture, self-report from those within a culture would likely not readily identify this factor.

Creation of Antagonists

In one case from Austria described in Table 1, "millions of Europeans" followed a battle depicted between those urging standard treatment, including then-President of Austria, and the considerable public contingent in favor of CAM (with support for "wonder healers" estimated at up to 46% in a local survey) (Jahn, 1995). Openness of conventional health providers to CAM may impact patient disclosure and potentially health outcomes (Martinson & Yee, 2003; McCurdy et al., 2003).

Same Chemo, Side Effects, and Percentages, but Different Views

In a court ruling from Chile, treatment refusal was allowed in light of a 50% chance of cure, which was characterized in this case as a low chance of success. In other HIC settings, there have been at least five other cases (Table 1) where chances of cure 50% or below (including one below 20%) were considered sufficiently high to warrant court involvement to enforce curative treatment. Similarly, chemotherapy has been described as being critical to sustaining life, or, conversely, as "an extremely risky, toxic and dangerously life threatening medical treatment offering less than a 40% chance for «success»" even in modern North America (In re Newmark v. Williams, 1991). Side effects, too, have been seen in different lights, not only as something to be avoided, but also as favorable signs of chemotherapy effect (Israëls et al., 2008). Such variable perspectives in different contexts support the promotion of health counseling as a key strategy for abandonment reduction, allowing for better support of families' understanding of patients' disease course. In light of these variable challenges, how might societal structures including legal governance support patients and families considering abandonment?

Legal and Ethical Considerations

The involvement of legal authorities affects the timeline and subsequent management in HIC differently than in LIC, where the infrastructure, social pressure and normative value for legal governance of abandonment typically do not exist.

Personal liberties and rights, including variable concepts of appropriate rights to be given to parents, adolescents, and minors, constitute central parts of discussions on abandonment in HIC. In particular, the right to choose alternative treatments, including CAM (Miller, 2009) and prayer, is much debated in the public domain.

The image of a 13-year-old with Hodgkin disease who is "pulling out catheters, refusing to allow her pulse to be taken and drinking a banned soda, thus halting the high-dose chemotherapy that was to be the next step…" (Associated Press, 2005, Sep 10) paints a colorful, but not unfamiliar picture that hints at the challenges of providing legal and ethical management in abandonment scenarios.

In practice, the role and value of legal governance in HIC has been variably characterized, veering from life-saving (Barisic, 2007) to unwelcome interference (Simpson, 2008). Legal actions taken to apply "the child's best interest" can result in conflicts that are perceived as unhelpful for the patient in both HIC and LIC.

In reviewing cases from HIC, it is apparent that different societies render different judgments of the appropriate treatment of adolescent versus parental decisions; the definition and rights granted to mature minors (for instance, whether a 15-year-old found competent may decide to abandon independently of his/her parents); the definition of legal age and whether age is used as a criterion for consent, as well as the responsibilities of guardians and health care providers. In one example, attempts to include a 15-year-old's testimony of desiring her treatment abandonment for religious reasons were dismissed, as only parental perspectives were deemed of legal relevance (Schabner, 2007); another 15-year-old's request for religious reasons was accepted both by his treating team and the court, with the acknowledgment of his status as a mature minor, even as the imminent outcome of death with abandonment loomed (Robb, 1994). Some have argued that patients may warrant being protected from themselves, especially for adolescents who may as yet have inadequate perspective (Mercurio, 2007). Legal arguments in at least one instance advocated for restriction of communication between parents and the adolescent in order to foster patient compliance (Associated Press, 2005 Sep 7). The issues of various interconnected rights, responsibilities, and ethical considerations have been raised (Caplan, 2007; AAP, 1994; AAP, 1997; Holder, 1992; Harrison et al., 1997; Hord et al., 2006; Hui, 2008; Spinetta et al., 2002; Carrese, 2006; Ross, 2009; Alessandri, 2011). Various permutations of potential conflict have been demonstrated and may be possible in HIC and LIC abandonment scenarios; participants outlined in Table 3 delineate potential complex conflicts (Table 3).

Perspectives from HIC

Abandonment cases have at times led to re-appraisal of the law and, in one case, even a new legal statute. Virginia passed "Abraham's Law" in the wake of a 15-year-old's decision with his family to forgo further chemotherapy for Hodgkin lymphoma (case details in Table 1); the state law specified that parents of a patient 14 years old and above with a life-threatening illness could refuse recommended therapy if specific conditions were met. The law stipulated that the decision had to be jointly made with the parents and the child in good faith, that it was in the patient's best interest, that the child was sufficiently able to make an informed decision, and that other treatments were considered (Mercurio, 2007). Challenges however, include that this left open the risk that untested or unproven treatments, or faith healing, could be chosen in lieu of proven treatments regardless of how good evidence-backed outcomes may be. There is irony in how allowing patients the right to choose may also deny them the very opportunity to exercise that right later (if they do not survive). Altogether, three initial key points emerge in evaluating the legal governance of abandonment situations. First, legal protection and governance is highly variable, whether across different court

Table 3. Potential Parties That May Be in Conflict in Abandonment Scenarios

Patient
Parents
Custodial guardian (not biological parent)
Other families of children with cancer
Multidisciplinary pediatric oncology health care providers (including physicians, nurses, pharmacists, psychologists, social workers, child life workers, trainees)
General health care practitioners
Providers of alternative health treatments
Hospital administrators
Court appointed guardian
Community leaders (formal leaders, including those assuming religious, political, or donor group leadership, as well as informal leaders)
Community advocates
Lobbyists
Media representatives
Legal counsel and representatives
Judges from differing courts (juvenile, lower, supreme, etc.)

levels or regional and national borders. Second, all involved in the care of children stand to recognize the legal protection in place in their locale, and advocate accordingly to bridge any gaps seen. Third, legal determinations may not always be associated with expected results, and potential precedents may be set with grave impact on other patients. Despite evident flaws in legal governance structures for patients in HIC settings, efforts must continue to uphold the rights of children everywhere to have access to life-sustaining treatment.

Perspectives from LIC

In most cases in the LIC, the institutional and legal frameworks to address abandonment are lacking, and in the cases where these are available, there are still many issues preventing the system from working optimally. The first time a new child protection law was applied in a case of cancer treatment abandonment in El Salvador can illustrate this. In 2009, a new law (known as LEPINA) for the protection of children and adolescents was approved.

Article 18th (translated from the original Spanish text) says as part of its measures to safeguard the right to life, that in the case of emergencies or potential irreparable damage to a child or adolescent's health,

> the doctor will ask the parent or authorized representative for hospitalization of or intervention for the child or adolescent, and in case of their absence or opposition, the provider may request the intervention of the General Attorney of the Republic, who must resolve [the matter] within a maximum period of twenty-four hours. (Ministerio de Gobernacion 2009: 8)

The intervention of the state was requested by the hospital when a couple refused cancer treatment for their child after hospital discharge. The resulting arrival of police to the child's home to take him and his mother back to the hospital immediately shocked and infuriated the family, who complained of maltreatment and turned in anger against the medical team and health and legal system meant to save and protect their child. Although this legal action brought the child back to the hospital, the trust relationship between the family and treating team, so critical for long-term cancer management, was irreparably harmed. Indeed, there is no way that typical cancer treatments can be provided without the agreement of the family given how most regimens require some treatments to be given at home, and warrants parents' and patients' involvement.

The support of legal and protective services is necessary, but best results can be achieved only with well-planned strategies in collaboration with the involved health care professionals. States or institutions seeking to implement such protection need to organize not only the creation of relevant laws but also the mechanism for applying the laws, and the resources to do so. Only when one attends to details such as who approaches the family, how this is done, and what resources can be made available to support families in response, can legal and social systems intended to reduce abandonment or harms to children head in the right direction. Thus, we believe that legal involvement is appropriate when abandonment has been reduced to a relatively low baseline level and the existing social infrastructure has sufficiently advanced to support its effective implementation.

In addition to legal perspectives, there may also be broader ethical mandates about how we ought to respond to scenarios of abandonment, particularly where families strongly desire not to abandon. One recent headline (Foster, 2011) portrays a glimpse of the challenges and inventiveness demanded of families in resource-constrained circumstances who seek not to abandon care. A Chinese mother of a young child with Retinoblastoma without sufficient funds for treatment crawled on her knees with her child on a busy street in China for a thousand meters, apparently in response to an online challenge that promised 20,000 yuan for the humiliation. As it turns out, the challenge was a ploy with staging and coaching by an employee with the Internet host site; amidst angry public responses and judgments, the employee who was fired insisted he was merely attempting to help – implying that, ethically, he was in the right in seeking the ultimate good of the patient's survival. The mother has since offered to return the significant donations she received (equivalent to more than 25,000 pounds), starkly greater than the sums she had been able to solicit for months online (38 pounds). The interesting question arises whether readers ought to be angry over the lie, or equally angry that families seeking to avoid abandonment of treatment for their children should have to seek such desperate measures for help.

Implications

There are various implications across the globe for patients, as well as families, providers, and the broader community in relation to treatment abandonment.

Patient Outcomes

In HIC, where early intervention often mitigated protracted treatment delays, abandonment was still associated with progressive disease or worsening of the patient's

prognosis in over 50% of the cases summarized in Table 2. Nevertheless, the dangers of abandonment, including potential resistance to chemotherapy and development of progressive disease, are only occasionally discussed in media depictions (Dorning, 2008; Belkin, 2009).

In resource-limited settings, failure to complete treatment has consistently been found to be a major reason for cancer treatment failure across different continents (Metzger et al., 2003; Frangoul et al., 2008; Luo et al., 2009; Moleti et al., 2011; Bonilla et al., 2010; Arora et al., 2010). In the context of accurate cancer diagnoses, death is expected from most cases of cancer treatment abandonment, with exceptions in cancers that are either highly responsive to even abbreviated treatment or very indolent. In direct attempts to follow up with families who have abandoned, Wang's team (2011) found very few (2%) to have survived among 191 families of children with ALL who abandoned over a 10-year period in China, while Sitaresmi's (2010) follow-up in Indonesia found 70% of the ALL patients who abandoned to have died within 8 months of abandonment.

Collective Impact of Abandonment on Patients, Families, and Providers

In addition to the deep suffering that may arise from negative health outcomes for those who abandon, irreparable disruptions of relationships, loss of faith, broken marriages, and loss of employment have also been among the social costs reported both in LIC and HIC (Gabor, 2003; Israëls et al., 2008). Patient-provider communication and relationships are also significantly impacted, thus further affecting patients' ability to make informed decisions (Robb, 1994). Providers often face deep moral conflicts in responding to abandonment as "forced care" seems to go against the very nature of wanting the best for a patient, with some providers even specifying that they would not go against a patient who has abandoned or refused care (Robb, 1994; Harrison et al., 1997; Belkin, 2009). In addition to posing significant stress, abandonment may also challenge providers to have specific resiliency and culturally-appropriate skills (Hinds, 1995; Tabak & Zvi, 2008). In HIC, the stress associated with such emotional responses may be fueled by public scrutiny and protests; in LIC, the recurrent and potentially daily wear of patient after patient abandoning can carry added risks of compassion fatigue and provider burnout. In either case, honest acknowledgment of providers' emotional responses is necessary so that emotions may be appropriately processed. Ideally, the goal should include ensuring that patients and families not feel "punished" for abandoning or returning, and that the focus remains primarily on patients' best interests from multiple perspectives.

The impact of abandonment may extend beyond a single case. For instance, it can powerfully diminish the morale of the medical team as well as other families undergoing therapy. This is often exacerbated in LIC, where patient abandonment is so much more common, and those who abandon may return later with progressive and more refractory disease (Abuidris et al., 2008) before succumbing to their illness. Both in LIC and HIC, other cases of abandonment may be cited by families, the media or courts and discussed as being helpful inspiration or cautionary tales, even a decade later or a continent away. For both families and treating teams, abandonment is highly inefficient, costing significant time as well as valuable resources that may ultimately be ineffectual. On a healthcare systems level, disagreements between team members and between working staff and hospital

administration regarding emotionally-charged abandonment scenarios can be associated with frustration and even potential anger and resentment against the workplace, even for those that may not be directly involved in the scenario.

Providers, when presented with specific scenarios, may respond differently to the dilemma of abandonment. Two separate surveys (Talati et al., 2010; Kent et al., 2011) based in the U.S. with almost 1500 practitioners combined, recently assessed the perspectives of pediatricians, pediatric oncology nurses and physicians on abandonment of childhood cancer treatment. Both studies showed that providers' acceptance of abandonment was affected by chance of cure and patient age, and parent-child agreement was also a finding in one study (Talati et al., 2010).

On a general community level, abandonment may also affect social perceptions, such as those of cancer curability or treatment toxicity, as well as impressions of health providers or health systems. In so doing, these effects may adversely affect general efforts to advance completion of treatment and cure for children with cancer.

Strategic Priorities and Next Steps

Given that abandonment of cancer treatment can occur in different phases of a child's experience with cancer due to different issues, collaborative and advocacy strategies may be more appropriately prioritized accordingly. An overview of some specific strategies are presented in Figure 4, representing sample anticipatory and ongoing priorities that may be most pertinent as a patient is being evaluated for their diagnosis (avoiding upfront abandonment), as a patient is undergoing treatment, after initial abandonment, and throughout their course. The principles behind these strategies may help re-affirm benchmarks in both HIC and LIC even as their implementation expectedly differs greatly. In many cases the priorities need to be addressed and implemented as a system and extend beyond care for a particular patient to the many patients in need (Figure 4).

Some aspects are more specifically pertinent in resource-limited settings, including: global and regional partnerships including twinning between HIC and LIC (Kellie & Howard, 2008); advocacy for human rights and access to essential treatments and services; adapted protocol-based treatments; the need for research, as well as for knowledge translation whereby established evidence is converted into actual relevant and achievable practices (Woolf et al., 2008); and strengthening of multidisciplinary management. Models illustrating strategic collaborations involving both HIC and LIC settings to reduce abandonment have been detailed elsewhere (Ribeiro and Pui, 2008).

Conclusion

Through exploring abandonment with individual cases in HIC in conjunction with data at a more macroscopic level summating patients' experiences from LIC, we have tried to elucidate different perspectives and issues concerning abandonment of cancer treatment in children and adolescents across settings and cultures. In doing so, we hope we have facilitated a different understanding of the complex factors underlying abandonment and its multi-

dimensional implications, and compelled readers to participate with us in endeavors that may reduce abandonment. Some key issues can be highlighted from the content above:

a) In LIC, the high burden of abandonment stands as testament to the gaps that have yet to be addressed in translating established, evidence-based, existing standards of care available for several decades in HIC, to LIC settings where most children with cancer live. Although it is far less common in HIC, the problem of treatment abandonment can similarly expose fundamental weaknesses in the health system which need to be re-structured.

b) In many ways, abandonment of childhood cancer treatment is a reflection of our collective societal values and priorities, our social and healthcare systems, and the quality of biomedical and psychosocial treatment we are providing.

c) Money is necessary to build and support solutions for abandonment, but it is insufficient as the only resource or intervention. Additional solutions, then, must be sought through challenging and testing assumptions and critical evidence-seeking research.

d) The multi-factorial nature of abandonment makes multidisciplinary involvement in the management and research of abandonment critical for every childhood cancer program. Knowledge, interpersonal skills, and collaborative team efforts are vital to the success of such multidisciplinary efforts.

e) Global and regional partnerships, such as twinning between resource-rich and resource-limited settings, are of utmost importance to helping to build capacity and infrastructure for ongoing health system improvements that would reduce the risk for abandonment.

Integral efforts to address the root factors as well as implications of childhood cancer treatment abandonment both in LIC and HIC can not only save the lives of children with cancer but also strengthen the health system as a whole. Each reader can help respond to the global imperative to reduce abandonment, whether through building awareness, joining in advocacy efforts, or engaging in partnerships. Our acknowledgement and response to abandonment can serve as a testament that compassion does transcend regional and national borders, such that improved survival for children with cancer is a tangible reality globally, and “defaulting” or abandonment of child cancer treatments no longer remains the “default” in any corner of the world.

Note

References for cases described in Table 2: Associated Press (2005, Sep 10), Associated Press (2005, June 10), Associated Press (2005, Sep 7), Associated Press (2005, Nov 1), Associated Press (1995, Jul 30), Associated Press (1996, Oct 10), Associated Press (2007, May 23), Associated Press (2011, Apr 12), Barisic, S. (2007, Sep 19), Belkin, L. (2009, May 11), Black, C. (2007, Nov 28), Blatchford, C. (2008, May 14), Boseley, S. (2008, Sep 12), Canadian Press (1999, Jul 2), Caplan, A. L. (2007), CNN. (2009, May 26), de Bousingen, D. D. (1996), Deutsche Presse Agentur (1995, Sep 19), District Court of Appeal of Florida (1994), Dorning, A. (2008, Jul 2), Gabor, J.Y. (2003), The Hep Review. (March 2010), Hui, E. (2008), Hunt, S. (2011, April 13), Illinois Supreme Court (1989), In re Newmark v. Williams. Supreme Court of Delaware (1991), In re Willmann, 24 Ohio App. 3d 191 (1986), Jahn, G. (1995, Jul 29), Jones, B., & Pesce, C. (2009, May 21), Leidig, M. (2004, April 21), Mahoney, J. (2008, May 12), Markon, J. (2006, July 26), Martinez, E. (2009, Jul 1), Mcnab, M. E., & Beca, J. P. (2010), Mercurio, M. R. (2007), Miller, D. M. (2009), Moore, M. T. (2006, July 11), Newfoundland Unified Family Court. (July 19, 1993), News-Herald. (2009, Aug 3), Robb, N. (1994), Ross, L. F. (2009), Schabner, D. (2007, Oct 3), Shephard, M. (1999, Jul 3), Simpson, E. (2008, Jun 5), Spencer, B., & O'Leary, C. (2009, Sep 4), Supreme Court of Tennessee, at Knoxville (2008, Aug 15), Supreme Court of Western Australia (2009), Times Colonist. (2008, Jun 21), Wasserman, S. (2010, Mar 28), Williamson, K. (2002, Aug 20), Wilson, B. (2007, Jun 12), WorldNetDaily (2003, Aug 29), WorldNetDaily (2003, Sep 10), WorldNetDaily (2005, Jun 9).

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Assessing the Ethics of Cultural and Spiritual Challenges to Informed Consent in Medical Practice and Research

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Abstract

Culture is one of the most common words in use today and yet it represents one of the most difficult subjects to define. For some, culture represents old ways of doing new things, while for others, it is what people live and feel in their human differences. These differences include thoughts about spirituality and morality. The inclusive nature of the term culture often makes it difficult for people to differentiate its application to various levels of human endeavor, including the field of healthcare. These challenges occasionally result in ethical dilemmas that complicate consent communications and may lead to the unintentional abuse of human rights. This paper will attempt to analyze differences in cultural expression and how they affect informed consent in medical practice and research.

Keywords: Ethics, culture, spirituality, medical practice and research, informed consent

Introduction

When one thinks of ethical dilemmas in the hospital setting, what often comes to mind are conflicts of interest and position. These include decisions about the right or wrong way to address a patient's treatment or refusal of treatment. Decisions about life and death are often—indeed most of the time—heart-wrenching processes that engage all our senses, especially our cultural and spiritual orientation. Avruch (1998), quoting Schwartz (1992), observed that "culture consists of the derivatives of experience, more or less organized, learned or created by the individuals of a population, including those images or encodements and their interpretations (meanings) transmitted from past generations, from contemporaries, or formed by individuals themselves" (p.17). Schwartz's understanding is

aligned with the anthropologist Sherry Ortner's categorization of culture as a mobile human commodity that gains its nuance through an individual's evolvement with new social realties (Ortner in Limov, 2010).

However, Ortner's opinion in *Practice Theory*, that persons are not defined by their culture, fails to recognize that culture is more than a symbolic identifier. Rather, culture has to do with group problem-solving skills that are exclusive to a language of reasoning. Dirks et al. (1994), analyzing the thinking of Clifford Geertz (1973, 1980, 1988), opined that "culture has to do with meaning, with the way experience is construed rather than with some unmediated notion of experience itself, with the centrality of symbols for formulating and expressing meanings that are pervasive and shared" (p.22). Therefore, culture resonates as more than a symbolic, stereotyping identifier, but essentially a group problem solving skill process.

In light of the foregoing analysis, and for the purpose of this essay, culture is defined as the sum total of all that comprises a people's way of life and existential meaning-making process. Spirituality, on the other hand, is the ritual language of expression of a segment of culture that helps individuals make sense of the unknown (God, gods, deities, spirit, life and death) as they impact human endeavors. Richardson (2002), notes, "Spirituality comes out in a humble loving attitude and life style towards others" (p.13). In the process of buttressing points of interest in this paper, spirituality as a language of experience may appear to be used as a concept restricted to organized religion, but that is unintended. Wherever there is human culture, no matter how profane, there is an outlet that connects human experience with the unknown. Just as every human being is cultural in their formative skills, so are they equally spiritual in essence. Spirituality "has to do with the quality of our relationship to whatever or whomever is most important in our life" (Bjoklund, 1983, p.3). In summary, spirituality is that vital, intangible aspect of life that attempts to meaningfully clarify and preserve the wealth of our cultural heritage.

Culture is an acquired set of skills transmitted from one generation to another through a defined and semi-defined process of value acquisition. Spirituality serves as a validation of those unwritten codes that are not easily explicable to the rational mind. Thus, spirituality is the thread that links the known to the unknown of human life experience. These synergies of inclusive culture create a lens through which we perceive and define our world. In "A new big five: fundamental principles for an integrative science of personality," McAdams and colleagues (2006) claim that our environment of evolutionary adaptiveness, narrative construction and differential culture roles is a major influence in molding our personality traits and life responses. In other words, those rational and irrational values acquired from family, schools, religious practices and rituals create a template through which we make meaningful responses to life's challenges.

In *The Spirit Catches You and You Fall Down*, Fadiman (1997) argues that individuals process their consent to medical treatment and even surrender to death and dying within the context of their cultural affinity. Whatever is accepted as a norm of morality within a patient's culture appeals to their sense of meaning making and guides their decision making process. Consider the example of members of the Jehovah's Witness who are asked to consent to a blood transfusion. A typical adherent of Jehovah's Witness will face death rather than undergo a blood transfusion from another human being. Though this may sound

irrational to some, it resonates with their sense of being and meaning-making from a cultural perspective. It has nothing to do with a balance of right and wrong, but with a validation of their sense of self. Unless one understands these cultural realities, intricate and avoidable ethical dilemmas will arise and take a toll on the good intentions of medical practitioners and families.

Because of these cultural challenges, medical practice must place treatment and research within the cultural context of patients and their families. In the light of these challenges and opportunities, this article will attempt to respond to fundamental questions on the significant roles that culture and spirituality play in the process of giving and taking informed consent in medical practice and research.

Culture and Spirituality in Medicine

Over the past century remarkable medical breakthroughs and the accelerated pace of technology seem to have brought the dream of health within reach and made the healing arts seem like a matter for science alone. Yet healthcare cannot be understood in isolation from its cultural heritage. The practice of medicine, the art of healing and the care of the sick are themselves cultural constructs because they are a people's expression of their search for a life free from illness, infirmity and death.

The field of medical research and practice is itself a cultural and spiritual response to the human challenge of illness, infirmity and death. In contemporary thinking, culture is sometimes dismissed as a code of outdated and outlandish behavior that is inconsistent with modern civilization. This mode of thinking most often finds expression in the language of modern science and technology, and relegates culture and its spiritual components to the background. Yet without culture, civilization itself is impossible. Culture is not a book on the library shelf; it is the sum total of the life experience, beliefs, values and the way of life of a living people. Culture and spirituality are intertwined. Augsburger (1992) observed that "culture embodies the authenticity and unique purposes of each community." For him, "each culture seeks to express a people's values, sensitivity, and spirituality" (p.7). In this context, religion and religious beliefs constitute a subdivision of culture that helps maintain philosophical balance for those who live and believe in that cultural space.

Cultural Assent in Medical Care

Before the advent of modern medicine, illnesses that a culture had no way of healing were defined within a spiritual context as either a curse or a manifestation of retributive justice, resulting from one's sin or an ancestral lineage curse. Thus, sickness, death and dying were understandable only within the context of communal and theistic interaction. Everything happens for a reason, either good or bad, the gods know. This mode of reasoning is evident in Semitic beliefs and practices that are identifiable in the early Jewish community and mentioned in biblical texts (e.g., John 9:2, on the cause of congenital blindness,). The Jewish Torah and other writings, such as Exodus 15:26 and the Book of Job, also discuss the divine causation of disease. The activities of physicians and other healers were perceived as divine activities in human life. Sirach 38:1–2 says, "Honor Physicians for their services, for the Lord created them; for their gift of healing comes from the Most High." Also, consider the Jewish basic principles of medical Halachic laws, mostly taken from the

Book of Deuteronomy, which most orthodox Jews hold very dear to their heart. These are both religious and cultural frames of reference, serving to define Jewish identity, especially when making an informed clinical choice (Halperin, 2004).

In some parts of West Africa, North Africa, and the Middle East, communities view illness and healing in a similar way from the point of view of faith and culture. Islamic beliefs and practices prevalent in these communities often present a significant framework for confronting questions about sickness and healing. Islam conceptualizes health and illness as a function of the divine. Consider Quran 6:17: "If God touches thee with an affliction, no one can remove it but Him." Other Quranic verses such as 26:80, 10:47, and 17:82 have a similar emphasis. These verses reiterate the close association between spiritual practices and healing. Needless to say, these religious concepts will have an impact on the decision-making process of people from these communities. However, it would be a logical blunder to assume that all Muslims within these communities accept the same ethical tenets on all issues, just as it would be illogical to expect the rest of the world to view medical ethics from the perspectives of the western world. For example, although artificial insemination is permissible in Islam in a general sense, Sunnis prohibit third party donation and surrogacy, and regard donor or surrogate children as illegitimate (Khan, 2003). Values like these transcend human reason to resonate with various cultural principles, and will affect informed consent in medical research and practice. Medical science can be understood as an expression of cultural values grounded in the spirituality of being a neighbor's keeper.

The practice of medicine as an expression of societal values and the speculation about the etiology of disease is as old as humankind. For example, "more than 10,000 years ago people practiced trepanation: a hole was made in the skull bone, possibly in hopes of alleviating the effects of head injuries or symptoms of mental illness" (*The New York Times Guide to Essential Knowledge*, 2007, p.395). What differentiates the prehistoric practice of medicine from modern medicine is the fact that modern medicine is based on evidence acquired through scientifically conducted clinical trials and epidemiologic studies of disease causation.

In contrast, most culture-based practice is divinized, with the emphasis placed on the spiritual causation of illness. In some cases, illnesses are understood to be evidence of the anger of the gods and require appeasement. If after appeasement the patient still suffers pain or dies, it is simply accepted as a matter of fate. Some traditional African and Asian communities, and perhaps some Christian and Islamic groups, still hold these traditional medical practices as sacrosanct today. For them, spiritual beliefs and medical practice are inseparable. It is the spiritual rituals (prayers and incantations) that give efficacy to whatever herbs or medicines are available for treatment. The Economic and Social Council Chamber (2009) *Panel Discussion on the Contribution of Traditional Medicine to the Realization of International Development Objectives related to Global Health* defined Traditional Medicine (TM) as: "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses." (p.1)

The world is fast becoming a global village. The rapidity of air travel and increases in immigration bring patients each day from diverse cultures around the world to healthcare facilities in the United States. These patients arrive with pre-coded beliefs and values about

health and disease that are foreign to western practitioners. Culture, coded beliefs and values are human elements that die hard. Education and social sophistication may shape such cultural values but not replace them. Spiritual attachment to illness is a phenomenon that is based on culture, not on education or social status. It is important to note here that different people relate and use the resources of their culture differently. Thus, persons from the same culture may approach certain consonants of their culture differently from their compatriots, depending on their level of education and life experience.

Although some people claim to have transcended their original cultural beliefs because of their social affiliation, when it comes to matters of life and death, their choices often align with their cultural beliefs and practices rather than their social ideology. In times of crisis individuals often move towards traditional medicine to complement western medicine, as if to identify with their historical roots for support and approval.

> In many developed countries, CAM [Complimentary Alternative Medicine] is becoming more and more popular. The percentage of the population, which has used CAM at least once, is 48% in Australia, 70% in Canada, 42% in USA, 38% in Belgium and 75% in France. In many parts of the world, expenditure on TM/CAM is not only significant, but also growing rapidly. In Malaysia, an estimated US$ 500 million is spent annually on this type of health care, compared to about US$ 300 million on allopathic medicine. In the USA, total 1997 out-of-pocket CAM expenditure was estimated at US$ 2700 million. In Australia, Canada and the United Kingdom, annual CAM expenditure is estimated at US$ 80 million, US$ 2400 million and US$ 2300 million, respectively. (WHO Traditional Medicine Strategy, 2002–2005, pp.1–2)

It may be tempting to explain away these facts as the results of economic pedigree or the rising cost of healthcare. However, the statistics of Canada, a country with one of the best healthcare systems in the world, (WHO, 2000) prove otherwise. When confronted by helplessness and the likelihood of death, individuals are usually tempted to explore those spiritual values that reinforce hope and minimize hopelessness. Thus, the concept of chaplaincy in the hospital setting and in the armed forces operational units is a quest for the validation of the human being facing death, dismemberment and disease.

Curing disease without paying attention to human needs for affirmation can result in producing a patient who is disease free but psychologically traumatized. In the New York Times article *"What Broke My Father's Heart?"* Katy Butler (2010) narrated the ordeal of her 79-year-old father, who had earlier rejected a pacemaker implantation while he was still competent to make such a decision. Nevertheless, Mr. Butler's standing decision was not respected; he was given a pacemaker when he could no longer decide for himself after a stroke. As the narrative went, life was never again the same for the patient, his family, or for his 77-year-old wife. In her discussion of her father's dissatisfaction with the pacemaker, Butler recalled the following dialogue she had with the suffering father:

> I don't know who I am anymore…. My father said he came to believe that she [wife] would have been better off if he had died. "She'd have weeped the weep of a widow," he told me in his garbled, poststroke speech, on a

> walk we took together in the fall of 2002. "And then she would have been all right." It was hard to tell which of them was suffering more (Butler, 2010, Pp. 1–2).

This is just one of many palpable examples of how aggressively treating patients without attending to their human needs can produce a psychologically traumatized sense of self. In a survey published by *Archives of Internal Medicine* in July 2004, it was observed "that 65 percent of physicians would not necessarily follow a living will if, for example, its instructions conflicted with the doctor's own ideas of the patient's prognosis or expected quality of life" (Henig, 2005, p.2). Henig notes that the survey report demonstrates an operational conflict of interest that occurs in hospital emergency rooms daily. While such attitudes may promote professional altruism, the example above shows that they can also undermine a patient's existential cultural needs. When struggling with such life and death decisions, healthcare providers must recognize that the patient's culture and sense of self may not regard death as the worst evil befalling any person. This could bring relief and unburden both the clinician and the patient/family in the process. Culture evolves out of the collective human experience and provides its members with life strategies to respond to their needs. Human needs within the medical ethical field can be understood as those ideals and values that aid individuals in attaining a comprehensive and balanced sense of self. Chief among these are religion and spirituality.

Religious Beliefs, Practices, and Medicine

Religion is an intrinsic part of culture that responds to people's questions about life, death and the afterlife by restoring hope and replacing fear and anxiety with the presence of a divine comfort that soothes human needs. Spirituality, on the other hand, is the language religion uses to express itself. This linguistic provision could be verbal or non-verbal or even just a feeling of satisfaction communicated from an unexplainable source. Because of the role these components of culture play in human life, they necessarily affect the medical field at a level no science can explain. It is not uncommon for individuals to express the view that they are spiritual but not religious. This may appear to be a contradiction because there is no spirituality without a religious base. Spirituality without religion is only conceivable if our understanding of religion is limited to organized entities like Christianity, Islam, Buddhism and Sikh. But religiosity goes beyond structured groupings to encompass any form of belief system that individuals hold dear to their existence. Secular humanism, for instance, is a religion in its own right and will impact an adherent's spiritual assent and influence their choices in various fields of life, including medical decisions. Every human being is religious because everyone holds spiritual beliefs that influence their choices and aid their responses to unexplainable or threatening life experience.

Kapogiannis and colleagues (2009) conducted functional magnetic resonance imaging (fMRI) studies to learn how religious beliefs are processed in the brain. They discovered that religious beliefs use the same evolutionary pathways as other cognitive thought processes and beliefs. One of these areas was the left middle frontal gyrus. Inzlicht and colleagues (2009) equally discovered that religious convictions had an anti-anxiety effect for the persons who held them. This team discovered that religious convictions correlated with reduced activation in the dorsal anterior cingulate cortex (ACC) during trials designed to increase anxiety. Increased dorsal ACC activation was an indicator of increased anxiety (Extracts from Johnson, 2010).

Kapogiannis and colleagues' (2009) research suggests that religious beliefs and cultural affiliations may play an important role in the healing and recovery of patients. Medical practice that dismisses these scientific and non-scientific associations misses an opportunity to understand patients as members of a culture who draw on their lifelong experience in order to bring meaning to their present situation. In *Man, Medicine, and Environment*, Dubos (1968, in Huth & Murray, 2006) noted that,

> Throughout history and whatever the level of civilization, the structure of medicine has been determined not only by the state of science but also by religious and philosophical beliefs. This is just as true of the most evolved urban and industrialized societies as it is of the most primitive populations. Like his Stone Age ancestors, modern man lives by myth. (p.255)

Effective and efficient medical practice is grounded in a robust culture of respect for life (individual identity), the myth of possibilities, and the spirituality of an inexhaustible, life-long search for an improvement in the conditions of human life.

The Culture and Spiritual Foundation of Medical Ethics

Medical ethics deals with acceptable norms guiding people's behavior in the field of science and medicine. Such norms come from a body of defined experience generated from people's cultural and religious concepts of good and evil. In *A History of Psychology: Main Currents in Psychological Thought*, Leahey (1987) wrote that whereas "psychology is concerned with how people behave… ethics is concerned with how people ought to behave." For him, "understanding how people should behave cannot entirely be divorced from describing how people do behave" (p.3). Leahey's categorization of the social context of ethics brings us to the centrality of the role of anthropology, sociology and theology in the field of bioethics. An anthropological ethics will enable the practitioner to situate individuals within the experience space that shapes their values and meaning making. A sociological approach to bioethics, on the other hand, will situate the meaning making process of the individual within the social context (culture, religion, and other social groupings) of interaction that sustains and empowers the individual's sense of self. Theological enquiry in bioethics seeks to unearth the individual's route to responding to questions about the unknown. These often include questions about the experiences of death and dying, disability and illness. Sociological, anthropological and theological enquiries in bioethics are, in their essence, only different paths of enquiry into how individuals live and provide answers to their concept of «do good and avoid harm.»

The concept of anthropological and theological inquiry in bioethics leads one to the discipline of harmonizing culture and spirituality within medical ethics. That enquiry that attempts to harmonize the context of people's spirituality and culture is the sociology of religion. The sociology of religion, in the context of bioethics, examines how the individual defines him or herself before, during, and after illness, and what role culture and religion play in that process. Knowledge of people's sociology of religion (culture and spirituality) enables the caregiver to enter into the mindset of the patient to correctly empathize rather than sympathize. Empathetic care giving comes when the caregiver attempts to enter into the cultural world of the patient's feelings of social and emotional constraints surrounding their

condition. This level of cultural connection compels the clinician to treat the patient as an individual affected by a disease rather than treating the individual as the disease itself. Such a model of practice reinforces the ethics of justice and respect for persons. In some parts of the world with high context cultures, like Africa, the Middle East and Asia, certain illnesses create such a stigma that the affected individual would rather die undiagnosed than bear the attendant social burden of shame and humiliation. For example, when HIV/AIDS was first discovered in certain parts of Africa, many of the first generation patients stated that they would rather die of the unknown sickness than disclose it to their allies (Meredith, 2005). They were more afraid of the sociological implications of HIV/AIDS than the disease itself. The same was true of leprosy in the early Jewish community and sexually transmitted disease in most religious communities today. In such dilemmas it may be obvious that the patient does not necessarily want to die prematurely but chooses what he/she perceives as the lesser evil as a result of the social burden of stigma placed on his or her shoulders by social or religious affiliations. In such cases, the provider's challenge lies in articulating those ethical principles that can illuminate the long-term burden that patients and family may endure as a result of their religious and socio-cultural background.

In "*Beyond a Western Bioethics*" Ryan (2004) argued that our current understanding of bioethics often leads us to frame questions in ways that exclude the socio-cultural context in which individuals live. For Ryan, such anthropological deficiencies create a gap in the field. What is needed is a practice that is socio-culturally inclusive and anticipatory. Because many patients are unfamiliar with western medicine and complex medical jargon, finding ways to correlate technical information with familiar experiences can help break through communication barriers between patients and their providers (Pauwels, 1995; Nace, 2009). This will ameliorate the ethical dilemma arising from misrepresentation (Teno, 2001, in Curtis & Rubenfeld, 2001).

Medical Ethics as a Cultural Norm

Legitimacy in human action is founded on norms that individual communities have come to define as acceptable behavior. Such authentications are often rooted in a culture that embodies the religious and traditional norms of their communities. Culture, in this context, can be understood as that vital space within which the human person exercises and achieves his or her potential. That social network aids the meaning making process of life. In the post synodal exaltation on *Centesimus Annus n.51*, Pope John Paul II observed that an individual's destiny is rooted in his/her ability to comprehend their environment and tease meaning from it. According to the Pontiff, "the way in which [the individual] is involved in building his own future depends on the understanding he has of himself and his own destiny" (Sirico & Zieba 2000, p.78). This self understanding is anchored in concepts acquired from one's immediate community and often influences judgments from conscience. Thus, the formation of conscience and human autonomy only finds authenticity within the limits of the individual's understanding of self and culture. When these rich resources are not considered during medical decision-making, patients feel personally thwarted because it denies them their spiritual connection to roots that they have come to cherish as their identity construct. For example, imagine what a Jehovah's Witness adherent might feel waking up with a bag of blood transfusing into his or her veins in the hospital. Even if this procedure was carried out under emergency conditions, the chances are high that the patient would feel violated because such activity failed to respect religious and cultural beliefs. When a case like this

arises, working with a proxy whose spiritual/cultural beliefs pattern aligns with that of the patient could be the best route to clinical cohesion.

Every human institutional practice is rooted within a socio-cultural context that creates a space for people to signify their uniqueness. Whenever individuals are confronted with the fear of the unknown it is these social and cultural resources that help create meaning and hope for them. People often define what happens to them based on their cultural perceptions of reality. Sickness, death and dying are often perceived as a mystery that has meaning only within a socio-anthropological context of the human interplay with the spiritual. For example, in the Judeo-Christian tradition the mystery of death and dying is only made intelligible within the context of God relating to His people. This further explains the high demand for sacraments among Roman Catholic Christians at the point of sickness, death, and dying. The Islamic Qu'ran is equally replete with passages referencing sickness, death and dying as a secret discernable through interaction with the divine. Some religions, like Buddhism in some parts of Asia, conceptualize death as the end of suffering and rebirth. For them, "to end our suffering we need to end our desire for existence, for non-existence and for sense pleasure. Nirvana is the end of suffering, because it brings an end to those desires and cravings. It also brings an end to our karma and all future rebirths" (Bhikshu Kusala). Furthermore, "Buddhist cosmology defines rebirth as the transmigration of karma from one life to another." Other religious affiliations like African Traditional Religion and Sikhism create a framework for their believers to evolve a normative ethics for addressing existential issues. While most African cultural beliefs emphasize collectivism in decision-making process (Magesa, 1997), the Sikh faith focuses on individual decision making based on logic and emphasis on prevention from a duty-based approach (Bakhshi, 2008). These different cultural and spiritual ideas of being naturally influence the choices individuals make about their lives.

Therefore, generating informed consent in either medical practice or research without a critical analysis of what is informing the reasoning pattern of patients and subjects can be fraught with fundamental ethical errors of social indifference. Social indifference here refers to lack of or deliberate avoidance of core questions that may reveal disturbing cultural identity beliefs and practices of individuals. If bioethical decisions are made in the supreme interest of individuals, then the fundamental question will be, "who is this individual and what are the resources that can be used as a lens through which his or her best interests can be best represented"? In essence, the human person is best

> . . . understood in a more complete way when he is situated within the sphere of culture, through his language, history, and the position he takes towards the fundamental events of life, such as birth, love, work and death. At the heart of every culture lies the attitude man takes to the greatest mystery: the mystery of God. Different cultures are different ways of facing the question of the meaning of personal existence. When this question is eliminated, the culture and moral life of nations are corrupted. (Contesimus Annus, n.24 in Sirico, & Zieba, 2000, pp.79–80)

In summary, context, content and a model of communicating consent should play a significant role in classifying what qualifies as ethical practice in medicine (Nace, 2009).

Without the richness of culture and the vision of the spiritual identity of the human subject, human beings become mere instruments for achieving an end, while the medical profession becomes a vague scientific endeavor.

Cultural and Spiritual Ethics as the Basis of Informed Consent in Medical Practice and Research

Because of its immersive concern for clarity and understanding of the nexus between what is and what ought to be, the epistemological basis for bioethics is hermeneutics, the art of understanding and assigning meaning to words and events.. Bloor (2007) analyzed how selective attention can lead to prolonged hospital stays when clinicians minimize cultural and spiritual cues about a patient's response or non-response to clinical decisions about treatment plans (Atkinson et al 2007, p.178). Discussions about ethics in biomedical practice and research often take practitioners to philosophical questions about how people conceptualize their moments of illness. These discussions seek to uncover the basis of what informs an individual's understanding of his or her particular situation in conjunction with how clinicians themselves conceptualize their ideas about sickness, death, and dying. The melting point in this interchange is what defines and give clarity to the ethics of research and practice.

> For the most part, the term «practice» refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term «research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. (Belmont Report, 1979)

Both medical research and medical practice can affect the quality of human life productively, especially when actors realize that they will be held accountable for their actions to promote the greater good and avoid harm. The concern of ethics is less about the result of these activities as it is about the process of attaining those ends. Medical ethics in themselves are not synonymous with social morality. "While morality is concerned with social moral acts that are acceptable to members of society, ethics seeks to elucidate and evaluate the reasons for justifying such acts as 'good or bad,' 'right or wrong'" (Echekwube in Ovienloba 2003, p.5). The framing of ethical principles is rooted in beliefs that are grounded in cultural norms and our natural obligation to some power greater than ourselves. That greater force appeals to human beings as natural law governing the life process. Different persons connect with this concept of natural law differently depending on their sense of the divine.

The bedrock of ethical principles, whether in medical practice or research or any other field of human endeavor, is the respect for the dignity and sanctity of human life. In essence, our sense of the sacredness of life is framed by our cultural reality and guided by

our consciousness of a power other than ourselves. Respect for persons, beneficence, and justice are basic qualities that the Belmont Report articulated as fundamentals that should ground informed consent in medical practice and research. Nevertheless, understanding how these concepts resonate with culture and spirituality is paramount in the field of bioethics. The doctrine of informed consent resonates normatively with the culture of respect for life and upholding of the inalienable dignity of the human person as a being with rights and obligations.

An ethics that preserves the concepts of human dignity, the inalienable rights of persons, and obligations is a spiritual affirmation of the identity of the human being. Observance of these ethical principles serves as a profound way to attend to the human person as an entity whose identity transcends its corporeal existence. Ethics seeks to protect the spiritual-cultural sense of self that creates existential meaning as a universal cultural obligation. Thus, authentic ethical practice in the medical field is ultimately a service to the human culture of life, validated by an objective sense of the non-corporeal dimension of the human (spirituality). The question, therefore, is not so much about to whose culture and whose spirituality we owe supreme allegiance as it is about our solidarity with a common root whose foundation and survival depends on our individual and collective contributions towards its solidity and meaning making. The violation of such eternal ethical principles as, "first, do no harm" not only defies the individual, it defies us all. This is philosophically possible because our personal existential justification makes sense only within the context of our realization that "we are" because "they are."

Cultural and Spiritual Challenges to Informed Consent in Medical Practice and Research

Culture and spirituality constitute an individual's language by which he or she processes those things of greatest personal importance. Conflicts arise when such intrinsic qualities are treated with suspicion or are overlooked in medical practice and research. Sullivan and Youngner (1994) analyzed the clinical, ethical and legal dilemmas that can arise when a patient's right to refuse treatment is called into question. However, their analysis treats life as a clinical, ethical and legal property rather than a journey or an experience whose template is both subjective and objective. Sullivan and Youngner's analysis subjects the individual's liberty to life to a purely theoretical debate, thereby excluding the patient's sense of self and meaning.

Policy makers, clinicians, ethicists and legal luminaries frequently conduct their analyses by focusing on what they consider as the exclusive objective value of life. By so doing they ignore those meaning making commonalities shared by individual patients with the rest of the human species. The subjective core of the patient's life is often minimized and treated with a deep sense of suspicion, and in some cases totally ignored as irrational. Szasz (1960) puts it best when he observed that most contemporary psychiatrists, physicians and other scientists consider individual differences "in personal needs, opinions, social aspirations, values and so on" as indications of incompetence and mental deficiency in life and death decision making. Although this tendency may not be applicable to all and sundry, we deceive ourselves if we dismiss it as irrelevant. The problem with a reasoning process that minimizes the individual's sense of self is that it inherently challenges the individual's right to be unique.

Individual uniqueness in the crowd touches on the concept of unity in diversity. Unity here refers to the commonality that persons enjoy with the rest of the human family. Diversity, on the other hand, implies a person's freedom to be and to pursue his or her life journey. This is a freedom that demands empathy rather than sympathy or criticism. In this context, beneficence can mean finding the space to uphold the individual's right to decide whether to live or not.

Ryan (2004) has rightly described today's world as increasingly buffeted by a «heightened sense of interdependence and intercultural fertilization.» This new world order is a challenge to modern medical practitioners given the new environment of practice that further taxes the emotional resources of providers and patients alike. Furthermore, interdependence and intercultural fertilization constitute a challenge for healthcare providers because they redefine effective and efficient medical practice. Healthcare requires more than knowledge of science and one's immediate culture; it demands providers and researchers with global identities. Globalized identity is one that is knowledgeable about an individual's immediate cultural origin while having at least a minimum dispositional knowledge of other cultural and spiritual realities beyond one's immediate environment. This extra demand for spiritual and cultural competence is a social pressure that can either make or break a practitioner's effectiveness.

Much attention has been focused on what to do when a patient decides (or is unable to decide) to amend his or her treatment plan with documents ordering "do not resuscitate," "discontinue treatment," "take off life support," and "no blood transfusion." These are important documents, but the question of how and when to observe these dos and do nots without violating the core principles of respect for persons, beneficence and justice is more important still. People's decisions about their association with medical practitioners are often influenced by their cultural and spiritual perception of what it means to be sick, treated, and healed. For example, African continent nationale high context culture is unique because of its pervasive similarities in spite of its Islamic and Christian infiltrations.

> In African religions and culture, health is not a personal matter but is related to the well being of the whole community. The right relationship with God and with the whole community gives peace. Real health is to be found in a balanced relationship between one's body, soul and spirit, between those around one, such as a harmonious relationship with the congregation and with the metaphysical forces of which God is the highest. Healing thus concerns the whole person in his individuality and community. (Prograis & Pellegrino, 2007, p. 95)

Persons from high context cultural backgrounds such as Africa, the Middle East and some parts of Asia may have problems in a western culture where autonomy and individual responsibility for health decisions are highly prized. The challenge is not so much about rational logic as it is about attending to the values of family, clan and community interests in decision-making. This type of cultural conflict may challenge clinicians and bioethicists who are naïve about cultural variations in individual articulations and beliefs. The experience of illness and wellness consists of a complex combination of individual and community interests. These complexities become even more apparent in cases involving children and incapacitated adults (Sweeting & Gilhooly, 1991–1992). Decisions for and on behalf of such

persons go beyond that of the immediate family to the multi-layered influence of the larger community. Sloppiness in the decision making process when dealing with persons highly invested in their faith and culture may complicate the care of the patient.

In some cultures, the apparent tardiness in attending to patient needs may be related to the time needed to perform rituals on behalf of the individual (Fadiman, 1997). Such rituals are perceived as important by the participants because they help to elicit the intervention of the gods of the land to whom the individual owes his or her life. Prograis and Pellegrino (2007, p. 96) note that, "for the African traditional healer . . . medicine was not enough to effect a cure without the presence of ritual that made medicine effective. Ritual was necessary because illness and cure involved the spiritual, not just the material." When situations like this occur, how does one resolve the issue of justice, beneficence and respect for persons? What constitutes respect for the individual and acting justly may mean different things in different cultures. At this point, a competent spiritual and cultural analysis of the party involved may serve as an icebreaker in the drive for an effective communication process. In Western culture, conflicts of interest are resolvable through state jurisprudence. However, attempts at legal resolution may be viewed with suspicion by people who make meaning in their lives only within the context of community interest and a community decision-making process.

Sanders (2007) cites several examples of experiences during the anthrax scare that affected the United States Postal Service and the United States Congress and led to the death of some Postal Service workers. One of the high points of Sanders's essay was his description of how persons in the Black community held to their beliefs of racial discrimination in healthcare delivery in the United States. This he claims to come from an association of their historical experience of being used as research "guinea pigs." Their suspicion about the genuine interests of the "White-folks" in the medical field not only reinforced their belief in divine healing as opposed to medical intervention, but they equally claimed their community's historical experience as a basis for rejecting anthrax vaccines (Sanders cited in Prograis & Pellegrino, 2007, p. 95). Individuals who were involved with this spectacle did not make decisions based on their singular interest but on their cultural, spiritual and community historical affiliations. It would appear that the best interests of the individual would have been to consider his own particular health endangerment and that of the wider community of Americans. However, when the chips are down ethnicity and cultural bonding often trump political and individual needs in favor of that which creates meaningful assent and identity for the individual. Such occurrences can definitely complicate matters for both bioethics consultants and clinicians in analyzing decisions on behalf of the individual while complying with the laws of the State.

Gender discrimination and the utility of gatekeepers create yet another cultural and spiritual issue that can pose a serious challenge to informed consent in modern medical practice and research. In some high context cultures, women are culturally perceived as incapable of making decisions on behalf of their family or participating in any form of research without the consent of a male. Thus, an ombudsman will always be required to advocate for the interests of women. Closely linked to the issue of gender is the concept of power balance in culture versus religion and group differentiation. Some women have been socialized to believe in their powerlessness as a divine design and a symbol of their identity. Any attempt to liberate them through empowerment programs and voice-giving in

the decision making process is often perceived as an affront to their identity and religious beliefs. Important and urgent decisions regarding critical health conditions may have to wait for the approval of the male figure in the family, even if this has to do with the woman's personal health. This perceptive injustice may snowball medical decisions in favor of the patient and offend the sensibilities of persons from dissimilar cultures. However, this is the reality of the new world order. It forces cross-cultural interactions even when they may be viewed as uncomfortable for the caregiver. Efficient care-giving now must work within the understanding of a patient's cultural background and map out strategies under which the individual will receive care with respect, beneficence and justice.

Conclusion

Culture and spirituality are of immense importance in medicine, but they have been inadequately studied because of the perception that they are incompatible with science and reason. This gap is echoed in the frustrations that clinicians often face in dealing with patients from non-western cultures who may be viewed as alienated and difficult (Duxbury, 2000; Nace, 2009). Physicians, nurses and psychiatrists often apply different strategies to maneuver their way through these complex cross-cultural situations that arise in their attempt to provide care. Occasionally patients and their families withhold information for fear or uncertainty about the reactions of their healthcare providers.

Glaser and Strauss (2009), discuss the problem of effective communication with patients who have exhausted their treatment options or who are terminally ill. The authors analyze the justifiability of silence when the clinicians themselves have declared the patient expectant and are just managing information within the clinical community to the exclusion of either the patient or the family. Bloor (2007) reviewed the ethnographic significance of the concept of social death and clinical death in the hospital setting and how these categorizations influence the treatment of patients by physicians and nurses. Sweeting and Gilhooly (1991–1992) describe social death as the experience of "those in the final stages of a lengthy terminal physical illness, the very old, and those suffering from loss of their essential personhood because of dementia or coma" that leads to their being treated as mere statistics.

Glaser & Straus (2009) further cited several examples of how "Physicians sometimes betray feelings of negligence or unease by the very brusqueness with which they reject invitations to talk while making medical examinations of patients who are fully aware of their own terminality" (P.98). Consider the example of a physician who rejected the plea of a mother to let her child die on a humane ground by keeping the infant alive under oxygen for as long as possible. When confronted by the mother, "the physician bluntly told the mother that a physician's job was to keep life going as long as possible, and that the decision to do so was his alone, not hers." (p.1000). The physician may rightly mean the best for the suffering child based on scientific wisdom but what is defied here is the power of the ethics of effective communication that nurtures and empathize. The physician was right; he was doing his job as he saw it! However, we have to question the mode of communicating that efficient care that both parties crave for. What were the costs and benefits of this service? When we focus more on professional protocols and statistics to the exclusion of the voice of the beneficiaries, the unspoken message is that person is dead to the system even though he or she is still biologically alive. This means that the personal needs and interests of the patient and family are less important than the interests of the caregiver. This is an example

of social death within the hospital system. Clinical death, on the other hand, is a state of being confirmed biologically dead by available medical resources. What medical professionals ought to do with the cultural and spiritual sense of sacredness of dead bodies and how they negotiate that with the family is another subject for research consideration.

The cultural hermeneutics of this analysis go far beyond the issues of treatment and non-treatment to the problem of our attitudes and beliefs about treatment and non-treatment and how those issues are communicated (Nace, 2009). These attitudes and beliefs directly affect one's ability to provide healthcare and research in an ethical manner with respect for persons and justice. It could be argued that what clinicians really do is try to avoid situations of conflict with either the patient or family members. As Edward and Mauthner (2008) indicated, "Ethics is about how to deal with conflict, disagreement and ambivalence rather than attempting to eliminate it." (p.27) In addition, one of the ways to deal with cross-cultural conflict in the healthcare setting is to attempt to understand the language of culture and spirituality employed by the patient or their surrogate. A bold step towards this end would be the formation of an integrative practice that enlists effective chaplaincy and social work services from the point of admission to the last stage of service needs. Given the spectrum of interest that people attach to their cultural values and spiritual beliefs, ethics consultants will find more intense cultural analysis an important variable to consider in their problem solving negotiations.

The Way Forward

In an environment where medical providers are often forced to practice defensive medicine to protect themselves against frivolous lawsuits, an efficient and integrative practice will have to use all available resources. These include the use of other helping professions to compliment physicians' efforts to explore medical issues and communicate messages. As noted above, culture and spirituality is more about meaning making to attain cognitive consonance and less about political correctness. Cohen (1997) contends that,

> Cultural meanings are subjective meanings shared by members of a particular cultural group. People in each country of the world develop their own particular interests, perceptions, attitudes, and beliefs, which form a characteristic frame of references. . . . Different cultural experiences produce different interpretations not shown in conventional dictionaries. (p. 27)

To get to the organic reference point of these cultural and spiritual resources, empathetic team working that clarifies interests and propositions using the various helping professions (chaplaincy and social workers) may serve a useful purpose. While the bioethics team assesses the consistency of decisions with the available policies and legal framework of their institution and the state, it may not be a bad idea for social workers to continue to engage the onerous responsibilities of helping the individual towards understanding the pros and cons of such decisions both in the present and in the future. This could be done by attempting to enter into the cultural and spiritual reference point of the patient and family in dialogue. Deliberate attention to this caveat will minimize the possibilities of being overtly critical and generically judgmental of the thinking pattern of the subject. Attending to these opportunities will further solidify the strength of whatever conclusion is arrived at by the end of the sessions.

Furthermore, chaplaincy and social work services may consider going beyond basic services of offering prayers and maintaining legal paper work towards that of providing an empathetic presence that nurtures, and builds the mental confident level of patients and families, towards the ability for emotional readiness in decision making. The core resources of the chaplains and social workers could further be directed at helping physicians and bioethicists to explore the spiritual and cultural background of the individual as a guide to attaining mental consistency with the decision process. Besides, even clinicians can find themselves in clinical situations that conflict with their personal religious or cultural values. Such a clinical arena provides a real opportunity for team dialogue and professional collaboration with chaplains. (Lampert, et al. 2010, p.1014) Chaplains are well trained in cultural competence. For example, most Indian Chaplains have considerable knowledge about religious variations in their culture of origin (Hinduism, Buddhism, Sikhism, etc). The same applies to chaplains from Africa and Middle East. Despite their religious affiliation they are often trained to be very much in tune with their surrounding culture.

Chaplains, in this model, work as agents who creatively, compassionately, and empathetically lead the patient to explore his or her beliefs as a validating support. Religious proselytization and threats of damnation must be avoided if the objectivity of a valid service is to be evolved. The validating negotiation sessions will have to be professionally tailored around what creates emotional and psychological room for personal peace in the decision making process. I will like to see the social worker, in this arena, as aiding the process by providing social service support through helping the patient attain clarity about the process in order to produce a substantial informed consent. The emphasis here is on team work that supports and strengthens an integrative system of healthcare management. An effective system will draw on the resources of additional professions to attain its goal.

The ultimate goal of attaining cultural and spiritual competence is effective and efficient communication. Such communication should improve patient satisfaction and save clinician time. It is likely that patients who feel that their beliefs are affirmed and validated by the medical care system will be more apt to be forgiving when things go wrong. This experience could lead them to ascertain that the institution truly cares about them. In addition, caregivers may experience improved appreciation from patients and their families, as they experience improved meaningful communication. This circle may, in turn, boost institutional team morale, motivation, job satisfaction, customer satisfaction, and retention. Cultural competence may well improve team work among clinicians, especially when working with people from different spiritual-ethnic and cultural backgrounds. Moreover, cultural competence can create an environment where patients are able to trust their clinical team because of the feelings of connection with them and thereby lead to greater cooperation with their treatment plan. This, in turn, may lead to better medical outcomes.

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Anthropology of Architecture: Designing for Culture in Tribal Communities

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Abstract

The design of a physical environment is heavily influenced by cultural variables. In fact, it can be argued that building design stemmed from the struggle of needs and resources in a given environment. As human cultures evolved, buildings became a reflection of traditions and social practices. This is true for tribal cultures. Designing environments for the Native American population has dramatic cultural implications. Tribal cultures are rich with traditions and social practices that are centuries old. The following paper explores the relationship between design and cultural practices. It will begin with a general overview of how traditions influence architecture and then, more specifically, healthcare architecture and follow with sample experiences where tribal cultures impacted healthcare design.

Keywords: Healthcare Design, Cultural Design, Native American Healthcare Design, Tribal Design.

Introduction

Across the cultural spectrum and throughout the modernized world, buildings and structures are used to provide shelter. Invariably, they are also used to serve important support functions such as commerce, entertainment, healthcare, and religion. Every culture has dwellings, marketplaces, places of worship, civic gathering spaces and medical facilities. In addition to their geographic locations and community roles, these buildings are physically and functionally unique because of their designs. Their physical esthetics are heavily influenced by the cultural values, beliefs and trends of the people who construct and inhabit them, making each structure as unique as its local culture.

This is especially true for tribal cultures. Designing any environments for the Native American population has dramatic cultural implications. Tribal cultures are rich with traditions, beliefs and values that are centuries old. Spirituality is interwoven into everyday social interaction, family structure and general practices, including healthcare. These observations must be taken into account in the administration of healthcare to tribal communities. Healthcare facilities that cater to the Native American population must be designed adequately to deliver care in a culturally-sensitive manner. The following paper will first review how cultural variables strongly influence design and, more specifically, healthcare design. Secondly, the paper will explore sample experiences where tribal cultures practices impacted healthcare design.

How Culture Impacts Design

Often, design decisions are reflective of the local culture. Lifestyles and social structure impact the way people use their shelters, which in turn, informs the building design. This is best understood through the study of vernacular architecture. *The Encyclopedia of Vernacular Architecture of the World* defines vernacular architecture as "the dwellings and all other buildings of the people." (*Encyclopedia of Vernacular Architecture*). These structures are built and occupied by members of the community with local materials, labor and resources. They are designed with first-hand knowledge of the building's intended use and how it fits within the context of the physical, economic and social environment. Cultural influence impacts the visual esthetic of vernacular buildings through the use of color, symbolism and materiality. Three examples of a culture's influence on regional architecture can be found in traditional Chinese architecture, Hindu Vastu Shastra architecture and the modern vernacular architecture of Australia.

An example of architecture with a strong, recognizable cultural influence is found in China. Traditional Chinese architecture conveys the culture through strong visual cues. It favors broad, horizontal complexes over tall, vertical structures (*Chinese Architecture*, 2011). Cultural hierarchy and imperialism are made evident through design. Opulence and importance are signified by bold colors, numerous tiers consisting of roofs and floors and security walls. Religion and ancient traditions also permeated trough every strata of the community. For example, every home located the entrance at the front and facing the east. A winding path led to a screen-covered entrance to keep the spirits out. It was believed that spirits traveled in straight lines and are deterred by curved paths and screens (*Chinese Architecture*, 2011). The design in ancient traditions are rooted in feng shui, an ancient Chinese system of design believed capture the power of both heaven and earth to bring

physical, spiritual and financial success (*Feng Shui Dragon*, 2011). Historically, feng shui was widely used to orient buildings and other structures. The practice fell in popularity during the Chinese cultural revolution of the mid 20th'century, but has since reemerged, especially in western cultures (*Feng Shui Dragon*, 2011) (Figure 1).

Figure 1. Photograph of the Forbidden City in Beijing, China, featuring bold colors, numerous tiers consisting of roofs and floors and security walls. Retrieved October, 01, 2011 from: http://drsavta.com/travelkosher/2009/05/into-the-forbidden-city-beijing-china/.

A second example of culture informing design, and similar to the practice of feng shui, is the practice of Vastu Shastra in Hindu architecture. Vastu Shastra is an ancient Indian science of architecture that incorporates nature, metaphysics, mathematics and spirituality to achieve harmony between the built and natural environment (*The Encyclopedia of Vaastu Shastra*, 2011). The practice is believed to bring good health and prosperity to the occupants (Vaastu International, 2011). Residential design features employed by Vastu Shastra to support the attraction of positive energy include designing square and rectangular houses; ascending a staircase clockwise with a total number of steps that can be divided by three with a remainder of two; providing an even amount of open space on the southeast and northwest; hinging the main door to open outside of the house instead of in; and including an even number of both doors and windows so long as the number does not end in zero, e.g., the number 10.(Lewis, R., 2009) (Figure 2).

The last example of cultural architecture resides in Australia. "To touch the earth lightly" is an ancient aboriginal proverb that became the underlying philosophy of the highly-influential Australian architect, Glenn Murcutt (lewis, R., 2009). To him, it meant "not disturbing nature more than is absolutely necessary" (Frampton 2002). Murcutt, the only

Figure 2. Photograph of Vastu Shastra rendering in Mansarovar, India, featuring square and rectangular designs, ascending a staircase clockwise, and an even number of both doors and windows. Retrieved October, 01, 2011 from: http://www.indianhomedesign.com/2011_01_01_archive.html.

Figure 3. Photograph of the Marika-Alderton House, a prototype dwelling for Aborigine communities in Northern Australia, designed in collaboration with the Aboriginal artist, Marika Alderton. The house is designed for extreme weather conditions while respecting the natural environment and positions the house to "touch the Earth lightly." (1994). Retrieved October, 01, 2011 from: http://craigowendab310.wordpress.com/part-a-archetype/.

Australian recipient of the Pritzker Prize—a top, international recognition in architecture—employed his philosophy to design a multitude of economical residential and cultural facilities that made a very low impact on the environment (Turtle, 2011). His material palette consists of inexpensive and readily available products and his designs are responsive to the changing seasons and climatic variables (Frampton 2002). In one of his most notable projects, the Marika-Alderton House, he created a prototype house, in collaboration with Aboriginal artist, Marika Alderton (Henderson, 2011). The project consisted of several design interventions to adapt to extreme weather conditions all while respecting the natural environment and contributing to the tropical landscape. In the end, he produced a stylish dwelling that was culturally-sensitive, sustainable and cost-effective for reproduction by the Australian government to house Aborigine communities in Northern Australia (Henderson, 2011) (Figure 3).

Culture and Healthcare Design

The United States and other developed countries are vastly becoming more and more pluralistic. As such, healthcare providers need to be culturally sensitive to a diverse group of users more than ever. "In healthcare, cultural sensitivity involves understanding the values, beliefs and attitudes of providers and patients during healthcare interactions." (Joseph, Keller, Quan, & Taylor, 2011). Specific healthcare experiences such as such as childbirth, acute procedures, treatment and recovery, continuing of care and even death are strongly tied to cultural values. (Joseph et al., 2011). All healthcare users, patients and their families, care givers and support staff, can greatly benefit from a well-designed and culturally-aware environment.

One example of culturally-influenced healthcare design is developing in Saudi Arabia, where a growing population of male and female Saudis are campaigning to create government-run hospitals that are exclusively for female patients, healthcare providers, administrators and support staff. The impetus behind the gender segregation is to "provide a clean, healthy and Shariah-compliant environment for women working in the health sector as well as well as increase job opportunities for them" (Al-Sulami, 2010). Many female healthcare professionals are ostracized or prohibited to study or practice medicine by family and members of the community because they are thought to participate in gender-mixing, a practice frowned upon in Saudi society. When implemented, the new hospitals will be designed to be gender-exclusive to accommodate the gender-segregated demands of the national culture (Al-Sulami, 2010).

Another example of a society's cultural impact on healthcare design is the new Mafraq Hospital in Abu Dhabi. The Emirate of Abu Dhabi has a recognizable cast system where the social infrastructure separates the royal family and other high-statured individuals from the remaining population. The new $2.2 billion facility, currently under construction for completion in 2014, was proposed to meet the demand of the projected population growth. The hospital will provide 739 beds, gardens and healing areas with water features and a visible connection to the outside environment on every level. A unique feature to healthcare design but a commonality in a class-conscious culture like Abu Dhabi, are the two royal suites and 32 VIP suites located on the upper floors of the central patient towers. Separate visitor and patient elevator cores were designed to reduce visitor and patient interaction as well as provide private, dedicated elevators to the royal and VIP suites (*Hospital Build*, 2011).

The final example involves safety-net clinics, community-based healthcare providers for low-income, uninsured and under-insured patients. Throughout the country, patient demographics at these clinics are comprised largely of ethnic minority groups (Coalition of Community Clinics Health Clinics, 2005). In their research to identify ways to design safety-net clinics for cultural sensitivity, Joseph, Keller, Taylor and Quan identified three design strategies that enable the delivery of culturally-sensitive care. The first is the location and accessibility of the clinic within the community. This was best exemplified by the South Central Foundation's Anchorage Native Primary Care Clinic in Anchorage, AK. In addition to offering primary care, this multifaceted clinic and community center provides free public services to all members of the community. The clinic includes a café for people to gather and socialize, sell native arts and crafts and have access to free computers. The second strategy is the creation of wayfinding systems that enable easy navigation for users. La Clinica de la Raza may have multiple locations throughout California, but with a wayfinding system in place visitors can use easy to locate signage and maps to facilitate navigation. The signage is trilingual and color-coded with symbols to accommodate diverse users. The third strategy is the design of clinical spaces large enough to support the families who often accompany patients. The La Maestra Clinic in San Diego, CA, and the Open Door Community Center in Eureka, CA, feature larger exam, waiting and consultation rooms, flexible partitions, television viewing areas, gardens and outside public spaces designed to support families (Joseph et al., 2011).

Delivering Healthcare in Native American Communities

Most would agree that incorporating culture into a design is essential, but does designing for a culture improve patient outcome or well-being? This question defines the ongoing debate that Indian Health Service (IHS) representatives, healthcare administrators and design teams face when working on facilities intended to provide healthcare to Native American communities.

It is critical to understand the context of this debate. Healthcare for Native Americans lags behind the rest of the U.S. population. Specifically, Native Americans are 770 percent more likely to die from alcoholism, 650 percent more likely to die from tuberculosis, 420 percent more likely to die from diabetes, 280 percent more likely to die from accidents, and 52 percent more likely to die from pneumonia or influenza than the rest of the United States (Lincoln, 2003). As a result of these increased mortality rates, the life expectancy for Native Americans is 71 years of age, nearly five years less than the rest of the U.S. population, Native Americans stand in a position where health status is improving little relative to national averages, including other minority groups (U.S. Department of Health and Social [sic] Services, 2000; Commission on Civil Rights, 2004).

These statistics are presented to emphasize the differences in the healthcare milieu for Native Americans today. This leads to question: How many of these statistics could be improved with appropriate facility design? There is no consensus as to the exact degree to which the care environment, lifestyle and health behaviors affect health outcomes. Nonetheless, IHS reports that "lifestyle and behavioral issues contribute to almost 70% of the diseases that occur at a higher rate in Indian country" (Grim, 2003). For architects and

designers it is valuable to understand that culturally-responsive building design can have an influence on patient behaviors and satisfaction. By establishing an environment that reflects specific cultural elements, patients may be more likely to seek medical attention early.

IHS faces significant problems with the retention and recruiting of qualified healthcare providers and the maintenance of aging facilities. To make significant strides in the improvement of healthcare for Native Americans, it must be recognized that this issue is more than simply medical treatment or new facilities. It involves a holistic approach, which considers education, housing, economic opportunity, as well as empowerment through self-determination and self-governance. Moreover, social and cultural barriers, including racial and ethnic bias and discrimination, have been linked to Native American health disparities. (U.S. Commission on Civil Rights, 2004).

IHS-funded projects must meet federal mandates, as established by IHS design requirements. The organization developed its own Health Facilities Planning software that provides a sanctioned space program based on specific demographic data for identified service areas. Any deviation from this prescriptive approach must be documented and justified with IHS serving as the final arbitrator on what deviation will be allowed. The auto-generated space program is then implemented through a series of template designs with standardized room configurations.

This automated and highly-defined design process is used across the country to design facilities for tribes with very different cultural requirements, creating a tension between the desire of IHS to deliver standardized buildings with the desire of tribes to have facilities tailored to their needs. As previously mentioned, relating healthcare environments and provision of care to local cultures may support better utilization.

Designing for Tribal Culture in Healthcare Environments

The architectural design process, especially for a complex building like a healthcare facility, requires balancing the needs and priorities of numerous groups. In many cases, these priorities may be in conflict. A critical issue in the case of these conflicts is the question of how the conflict is resolved. At its most basic, it is a question of power—who has the power to make the final decision? Designing within the IHS system brings the question into sharp relief, as the design process involves balancing the regulatory requirements of IHS with the cultural requirements of the tribes that will use the facility.

Design projects that require, at minimum, the consideration of incorporating culture into a specific design solution raises many questions and requires careful exploration and consideration. For example, tribal cultural differences present varied design challenges. What is appropriate for one may not be for another. If culture is incorporated in the design, to what extent do users recognize the cultural references? Is it as simple as applying symbolism to a façade? Does applying this symbolism matter in a measurable way? Or, does selecting culturally-significant materials have more of an impact? How does the form of a tribe's historical buildings inform us? All of these questions and many others require additional study and research.

It is extremely important to understand the design firm's process and be able to adjust it, as required. For example, an exercise/activity in discovery of a tribe's vision, principles, and values that is suitable for tribe A may not be appropriate for tribe B. While this differs amongst groups, this example has more to do with what a tribe values and how they operate within their own tribal culture. How that is understood and responded to in a sensitive and honest way is extremely important to an architect's relationship with the tribe.

The cultural aspect of design is additionally complicated when, as is usually the case, the architectural team does not include tribal members. Although tribal members are generally consulted during the design process, the architect is still responsible for finding a way to incorporate cultural needs into the design. Maintaining good health and caring for the sick embody some of the strongest and most complex beliefs and practices in any culture. As an outsider, an architect cannot hope to develop comprehensive knowledge of these beliefs in the time generally allotted for a design project. Furthermore, in some tribal cultures, such beliefs would not be shared with an outsider. To overcome these obstacles, the design process must offer an atmosphere of empowerment, so that tribal members and healthcare providers are able to properly express their goals for the design process. To this end, the design process must include:

1. Respect for the unspoken. Some beliefs are too private to share. The design team must understand that some requests may not be explained in detail, and that it may be rude to ask for more information.

2. Do not make assumptions. Making decisions without the input of the community can be perceived as stripping their empowerment. In addition, correcting a wrong assumption can prove costly to a project's budget and schedule.

3. Provide varied avenues for feedback. Large group meetings may work well for a general overview of a project but smaller, targeted group meetings may encourage more participation.

4. Be patient with communication. Often times, a point is best delivered in the context of a story. Take time to listen thoughtfully and look for cues. Be cognoscente of the fact that even though you may speak the same language, there are cultural subtleties that cannot be absorbed during the typical design process.

As members of a design team, the vital step towards project success is to reach a level of understanding. This requires active participation as a facilitator and even greater participation as an active listener.

During the design stages of a project, acceptance of IHS-prescribed facility requirements by tribal leaders is often better achieved when rooms are discussed in terms of their use rather than their assigned names. The reason for this distinction is to support future opportunities to change the rooms' uses and to move beyond the notion that once a room is defined as a "Storage Room" it must always be used as such. This notion of adaptability can reassure participants and remind them that today's decisions can be modified if their needs change.

Sample Experience #1: Emergence Education in Tribal Culture

A design team, which included one of this paper's authors, was selected to design a major hospital renovation in Northern Arizona. Before commencing the project, the design team underwent a one-month "cultural emergence" with the local tribal community. It was a mutual feeling amongst all involved that the experience would afford the architects an invaluable opportunity to better understand concepts of health and wellness as they relate to values, lifestyles and traditions. This cultural immersion included exploring tribal language, art, food and customs. This was accomplished though meeting with community leaders, traditional healers and family members, in their places of worship, restaurants, community centers and homes. The design team took part in unique cultural practices, which included cleansing in a sweat lodge and spiritual storytelling, to help understand tribal healing philosophies.

The emergence experience helped inform final design of the hospital expansion on multiple dimensions. First and foremost, the morgue was to remain stationary out of respect for the deceased and the entire expansion was design around it. The expansion also provided a space at the hospital entryway for a traditional healer to practice healing arts like drumming, meditation and herbal cleansing. The program added new departments for health promotion and disease prevention to support diabetes, substance abuse and obesity education. The in-patient rooms, which also included a traditional healing room, were designed to provide access to nature as well as more room to accommodate family and friends. In the end, the emergence experience gave the design team greater insight to deliver a comprehensive and efficient healthcare program that incorporated design features that are reflective of the local culture. This understanding and sensitivity produced a facility that is welcoming to the community.

Sample Experience #2: Translating Culture to Design

An architecture team was awarded a new 70,000 square foot outpatient clinic for a tribal community in Oklahoma. The project was an IHS/Tribal joint venture. Prior to the award, the design team and the tribal owner had no experience working together, but the design team had recently completed several projects for another tribe. The previous tribal

Figure 4. The seven pointed star and seven columns are significant cultural references and pay tribute to the Tribe's storied past as well as their traditional heritage. The wood slat ceiling is configured similarly to that of the Tribe's historic Tribal Council building. Shields Marley Photography.

Figure 5. A culturally significant symbol representing water was incorporated throughout the exterior and interior of the facility. Water has significant meaning to the Tribe but also in this case the location of the facility sits adjacent to the confluence of three rivers in the region. The rivers played a role in influencing growth in the southern half of what is today a 14 county district. Shields Marley Photography.

owner requested the design team to incorporate cultural symbolism into the architecture of their projects. The symbolism included, cultural references and artwork prominently displayed so as to tell a story. In essence, it created a sense of place through cultural identifiers and references (Figures 4 and 5).

In the initial pre-design meetings, the design team discovered that their new clients' culture so profoundly defined who they were it was uncomfortable for them to consider it as an option for public display. To accommodate this situation, the design team made an adjustment in the design process to focus more on what they valued as a tribe. They asked tribal member participants to define what makes them who they are as a people. Their responses were categorized and included characteristics such as "honorable," "humble," "honest," "full of integrity," and "strength."

The next step involved translating this information into a design concept by identifying elements of the design that could correspond to who their collective attributes. The designers then utilized these elements to create a facility that expressed honesty and exuded strength. Exposed structural elements from floor to ceiling and visible columns in

Figure 6. Exposing structure was an important design feature and represented the idea that being honest with the structure and how the facility is put together best represented the Tribe's character. Image courtesy of Tangram 3DS, LLC.

the public spaces were visible translations of their values into facility design. The architects also took time to detail the exposed structure in a way that paid respect to specific tribal values identified during the pre-design phase. Building materials were selected from those considered honest by the tribe. They were indigenous to the region and related to the earth. (Figures 6 and 7).

This is a very simple but important example of how an understanding of what "designing for a culture" really means. It does not mean that every project is adorned with symbolism and interesting imagery. It does not mean that you need to tell a literal story. It means that design leaders must approach every project with an attitude of service and with the respect it demands by truly and honestly listening to the client in order to respond to their facility needs and improve their community.

Figure 7. Glazing was introduced at the main public corridors as a secondary reference to the Tribe's transparency of character or truth and honesty. Image courtesy of Tangram 3DS, LLC.

Sample Experience #3: Honoring Cultural Imperatives and IHS Mandates

While working on a recent space utilization and planning study for the expansion of a tribal healthcare facility, the design team came to the realization that the IHS planning guidelines did not take the local community's cultural consideration into account. The guidelines are designed to respond to all people equally and consistently but the reality is that tribes are not all alike. It became the responsibility of the design team to find a correct balance.

The hospital was located on a hill with fantastic views and the site was also an archaeological resource. The design team's first planning challenge was determining how to adapt a template approach to such a special site and remain sensitive to the site? Tribal traditions did not allow discussion of the site archaeology, but the designers needed to find ways to work around this and other issues that touched on closely-held cultural beliefs. There is a potential for inappropriate design responses when non-tribal design team participants make assumptions. For example, a tree damaged by lightning was assumed to be important by some of the non-tribal members involved in the project because of its location. After five attempts to develop a functional plan designed around the tree, the design team discovered that the tribe, in fact, wanted it removed because they considered it a negative element on the site.

During this project, the design team also concluded that the IHS's automated Program of Requirements (POR) process led to solutions that don't fit with the reality of facility operations. The planning program outlined a need for large dental clinic. This "requirement" was challenged by the local administration knew they could not recruit enough staff to operate this facility based on their previous failed attempts to bring dentists in-house.

In the end, the design team learned that working in another culture requires greater investment in the planning process in order to assimilate the information. It is not appropriate to rely on a shared set of assumptions. One may be required to ask more basic questions to get to an extensive, thorough level of understanding.

Conclusion

For architects, designing culturally-sensitive projects with the knowledge that they benefit underserved populations can bring much honor. On an idealistic level, these projects often become a vehicle by which users may identify, through design, their cultural worth and ultimately their own self worth. This is not something which can be measured directly. The value of giving a culturally-appropriate healthcare building to a population in need can be realized best through its very acceptance by the community. If the goals of healthcare providers are to control infection, cure disease and improve the overall quality of life for all, it is imperative for them to have increased access to the total population. Culturally-aware and responsive healthcare environments are one tool for broadening the reach and creating a greater impact on the underserved and often untouched segments of the population.

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Compassion and Ethics:
Scientific and Practical Approaches to the Cultivation of Compassion as a Foundation for Ethical Subjectivity and Well-Being

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Abstract

Recent years have seen a rapid growth in interest in the study of meditation and its health benefits, attention now broadening beyond simple relaxation techniques to other forms of meditation that involve the cultivation of positive mental states and emotions such as compassion. The scientific study of compassion suggests that compassion may be of crucial importance for our individual physical and psychological health. Moreover, because compassion relates fundamentally to how we as human beings relate to one another, its cultivation entails an ethical dimension that may be just as important as the medical and psychological dimension. In this article we supplement the emerging scientific literature on compassion by laying out a case for understanding compassion as a moral emotion intimately tied to the question of ethics and the cultivation of ethical sensibility. Second, we examine the individual and social benefits of compassion that support such a view. Thirdly, we describe in detail one method for the cultivation of compassion: Cognitively-Based Compassion Training (CBCT). We conclude by presenting current research programs employing CBCT and point to possible future directions in the study of compassion and its cultivation.

Keywords: compassion, empathy, ethics, meditation, education

Introduction

Recent years have seen a quickly growing interest in the scientific study of contemplative practices. Although much of this work has dealt primarily with meditation techniques for quieting and focusing the mind as a tool for reducing stress, increasing attention is being paid to styles of meditation that actively cultivate positive emotions such as compassion and that also appear to have significant health benefits. The scientific study of compassion and of methods for cultivating it is important for numerous reasons: First, compassion may be of crucial importance for our individual physical and psychological health. Second, compassion relates fundamentally to how we as human beings relate to one another when it comes to questions of happiness and suffering. As such, compassion and its cultivation have an ethical dimension that may be just as important as the medical and psychological dimension.

In this article we offer a supplement to the growing scientific literature on compassion by laying out a case for understanding compassion as a moral emotion intimately tied to the question of ethics and the cultivation of ethical sensibility. Second, we examine the individual and social benefits of compassion that support such a view. Thirdly, we describe in detail one method for the cultivation of compassion that draws from this view: Cognitively-Based Compassion Training (CBCT), an intervention designed to improve well-being and ethical sensibility by leading participants through a systematic process to cultivate powerful and unbiased compassion to others. Fourthly, we provide an overview of our current research programs employing the CBCT method in elementary school, foster child, adult, and other populations, and point to possible future directions in the study of compassion and its cultivation.

Compassion and Ethics

Today in the early years of the 21st century, the common global situation of humanity is such that the question of the place of ethics in our world is perhaps the most central question of our time. An analysis of the most pressing problems facing humanity, whether they are political, economic, social or environmental, shows that their causes lie fundamentally in human choices, and those choices are largely shaped by values. Ethical principles and values, however, can neither be bought through economic means nor legislated and enforced through policy and laws. This means that the solution to such problems can not merely depend on legal, political and economic systems or the reform of such systems (although naturally such reforms could still play a beneficial role), but also needs to involve the inculcation of values that reach the level of inner conviction. This is above all an ethical task.

> *Note 1.* Although contemporary understandings of secular ethics are often restricted to agreed upon practices separate from the emotional and moral subjectivity of individuals, as in the case of much of contemporary medical and bioethics, the broader view of ethics presented here is in fact very old and can be seen clearly in pre-Socratic Greek philosophy, where philosophy meant more than a set of principles or abstract truths about the world, but rather referred to a way of life that brought well-being and flourishing, embodied in the being of the philosopher-teacher to his or her students. For a lucid examination of how pre-Socratic philosophy gradually shifted from this ideal, see Pierre Hadot's *What is Ancient Philosophy?* (Hadot, 2004). The observation that all people (and even animals) seek well-being and happiness, rather than suffering and misery, has been made by philosophers and religious thinkers throughout the ages, ranging from Aristotle to St. Augustine. It is agreed upon as a foundational maxim even by individuals who hold wildly differing worldviews and views on religion, such as the present Dalai Lama and the outspoken critic of religion, Sam Harris.

Here we are understanding ethics broadly, whereby ethics is not merely confined to an external code or a set of principles of right and wrong, or correct and incorrect practices (which, when upheld, can lead to harming others instead of helping them). Ethics can instead be understood more broadly as a way of conceptualizing how human beings relate to one another and their environment with specific regard to suffering and its alleviation. This

is because, despite all the cultural and religious differences that may seem to stand in the way of a common ethical ground for human life and interaction, one thing that humanity shares in common is the wish for happiness and well-being for oneself and one's loved ones, while not wanting harm or suffering for oneself and one's loved ones. Importantly, this general definition of ethics can apply to anyone regardless of religious belief or lack thereof. Moreover, such a definition shows that, since suffering and its alleviation are chief concerns of individuals and societies irrespective of place, time, religion or culture, ethics must be a principle concern of human beings everywhere. Although broad, this definition is not so all-encompassing that it ends up rendering nothing ethical by rendering everything ethical, since there will naturally be actions that have a greater impact on human suffering and its alleviation than others. Furthermore, since the outcomes of actions can be difficult to predict, the role of intention and motivation is important.

If we adopt this perspective on ethics, we see the centrality of human values and in particular values like compassion. Compassion is a deep feeling of wishing to alleviate the suffering of others (Gilbert, 2005; Goetz, Keltner & Simon-Thomas, 2010; Gyatso, 2001). Compassion can serve as a fundamental basis for human values and ethics, precisely because a central problem of ethics is suffering and well-being. When compassion is present in a person's mind, that person cannot harm or further the suffering of the people to whom they feel compassion; on the contrary, their actions will work towards the alleviation of those persons' suffering. When compassion is absent from a person's mind, that person can engage in actions that are harmful to others if they benefit the person him- or herself. It is such self-serving actions, absent of compassion, that are responsible for most of the world's ills, whether they are economic inequality, armed conflicts, or environmental irresponsibility. This is likely the reason that His Holiness the Dalai Lama has suggested in his book *Ethics for the New Millennium* that compassion can serve as a foundation for a "secular ethics," by which he means not an anti-religious ethics, of course, but rather an ethics based on fundamental human values irrespective of a person's religious beliefs or lack thereof (Gyatso, 2001).

Two central questions, or sets of questions, therefore emerge. First of all, is it true that compassion is beneficial for an individual and a society, and if so, what are those benefits, and do they outweigh the costs? Secondly, if compassion does have benefits that outweigh the costs, then is it something that can be individually and socially cultivated? Up until recently, such questions could only be addressed philosophically or theologically, but an emerging science of compassion is beginning to address these questions in a practical way.

The Scientific Basis for Compassion

In his recent book *The Age of Empathy*, primatologist Frans de Waal surveys a growing body of empirical evidence to argue that our common perception of evolution as a Machiavellian or Hobbesian story of "every creature for itself," with a self-centered drive for individual survival as our most basic instinct, is largely distorted, if not altogether wrong (de Waal, 2009). For de Waal, empathy is a crucial ingredient and basis for feeling compassion for others, and in line with the presentation made above, de Waal sees empathy and compassion as fundamentally moral capacities. He makes the case that the roots of moral sentiments go back quite far in our evolutionary history: in his opinion, at least as far back as the last common ancestor of birds and mammals, since both benefit from maternal care of offspring (F. de Waal, personal communication). Morality, de Waal argues, rests on an ability to empathize

with others, and this in turn depends on an ability to take another's perspective (cognitive empathy) and resonate with them emotionally (affective empathy). Although de Waal does not claim that full-blown morality and empathy are present in non-human primates and other species, he does see plenty of evidence for their pre-requisite capacities, namely motor mimicry, consolation behavior, cooperation, a sense of self, and targeted helping (de Waal, 2009).

De Waal argues that his work shows that human nature is not rotten at the core while covered by a thin veneer of morality, but rather that the roots of empathy, compassion and morality run deep in our evolutionary history. If so, it should come as no surprise that they also seem to run deep in our developmental trajectory, as shown by the work of developmental psychologist Philippe Rochat. His work on the early development of empathy, self/other distinctions, and social cognition illustrates a powerful need for affiliation from infancy on. This "basic drive to be acknowledged in one's own existence through the eyes of others" (Rochat, 2009, 314) in turn gives rise to what Rochat calls "the mother of all fears," namely the fear of social rejection and isolation, which can lead to all manner of ills. Cacioppo and Hawkley (2009) note that, "Research indicates that perceived social isolation (i.e. loneliness) is a risk factor for, and may contribute to, poorer overall cognitive performance, faster cognitive decline, poorer executive functioning, increased negativity and depressive cognition, heightened sensitivity to social threats, a confirmatory bias in social cognition that is self-protective and paradoxically self-defeating, heightened anthropomorphism and contagion that threatens social cohesion." The fact that loneliness and perceived social rejection and isolation can even lead to suicide (Ozawa-de Silva, 2008, 2010) should be evidence enough that as human beings our need for social connection and acceptance is just as strong, if not stronger, than our instinct for survival.

Thus, there is good reason for the change in our scientific and philosophical view of human nature away from one of self-centeredness and isolation to one of social connection. As Jackson, Meltzoff, and Decety (2005) point out, "Evolutionary, developmental, social, and neuroscience perspectives stress the importance for survival of investing positively in interpersonal relationships, and understanding one's own as well as others' emotions, desires, and intentions." Recent work in mirror-neurons, although preliminary, is being interpreted to present even more evidence for this (Jackson, Meltzoff, & Decety, 2005), but they likely form only one part of a larger emerging picture. As Rochat and Passos-Ferreira write, "Human sociality entails more than the equivalence and connectedness of perceptual experiences. It corresponds to the sense of a shared world made of shared values. It originates from complex 'open' systems of reciprocation and negotiation, not just imitation and mirroring processes that are by definition 'closed' systems" (Rochat & Passos-Ferreira, 2008, p.191).

This change in our perception of human nature, suggesting that we are evolutionarily and neurologically "wired for connectivity," allows us to better make sense of why practices that enhance our sense of connectivity with others, such as compassion training, might show positive effects on our physical and mental health. In a study of adepts who engaged in long-term compassion training, Lutz and his colleagues found that the adepts generated strong activation in the left prefrontal cortex, a brain area associated with positive affect and feelings of well-being, when they engaged in compassion meditation, as well as levels of gamma synchrony previously unrecorded in non-pathological contexts (Lutz, Greischar, Rawlings, Ricard, & Davidson, 2004; Lutz, Brefczynski-Lewis, Johnstone & Davidson, 2008). In a study employing the CBCT method for cultivating compassion

that we will discuss later in this article, members of our research team found that training in compassion even among beginners results in significant improvements in immune function in response to psychosocial stress (Pace et al., 2008, 2009). Social and clinical psychologists have reported psychological benefits that arise from the related practice of self-compassion (Neff et al., 2005, 2007). Neff (2011b) writes that research suggests that "self-compassion provides greater emotional resilience and stability than self-esteem, but involves less self-evaluation, ego-defensiveness, and self-enhancement than self-esteem." More broadly, scholars in the health sciences have begun paying an increased attention to the important role empathy plays in health care (Larson, 2005; Norfolk, Birdi, & Walsh, 2007); medical anthropologists have argued for the need for an increased focus on questions of existential suffering and moral experience in medicine and care-giving (Halifax, 2011; Kleinman, 2006; Ozawa-de Silva & Ozawa-de Silva, 2010); and the study of non-western medical systems, such as Tibetan medicine, suggests that when such systems conceptualize the mind and body as interdependent, rather than separate and unrelated, compassion can be seen not merely as part of a so-called "placebo effect" but rather as a central element of patient care with effects on health outcomes (Ozawa-de Silva & Ozawa-de Silva, 2011).

While scientists in diverse fields are more recently pointing out the importance of compassion for human happiness and well-being, the idea that the cultivation of a prosocial moral subjectivity is essential for the good life is very old in the history of ethical thought, both in the west (Hadot, 2004) and the east (Gyatso, 2001). In the view of the Dalai Lama, one of the champions of the idea of compassion as a foundation for ethical thought and action, this is fundamentally because the essence of a meaningful life lies in not harming others but rather, if possible, benefiting them (H.H. the Dalai Lama, public talk, July 9, 2011, Washington DC.). As he points out, having a warm-hearted attitude and a sense of affection and caring toward others eases our communication and interaction with others, since we tend to see others more as potential friends and fellow human beings rather than potential enemies and "others" who are alien, strange and different to us. Seeking others' well-being means that one is far less likely to engage in behaviors that promote self-interest while harming others. Since such dishonorable and unethical actions always have to be hidden from public view, one consequently also has fewer secrets to hide from others, allowing one to be more transparent and open in one's interactions with others. This in turn brings self-confidence and trust in one's relationships, and that trust brings genuine friendships. Since we are social beings, it is no surprise that the presence of genuine relationships is correlated with more happiness, flourishing and well-being (Cacioppo & Hawkley, 2009; Keyes 2005, 2007). Moreover, if one has peace of mind and compassion, then even serious problems may not appear overwhelming; thus, such qualities may be key components of resilience, which is in turn intimately related with well-being.

On the other hand, if one is overly self-centered, then one engages in actions that promote one's own interests even when they harm the interests of others. This results in feelings of guilt and worthlessness, as well as a need to hide one's actions from others, which prevents transparency and openness in one's relationships. Since one takes advantage of others, one naturally suffers from a consequent lack of trust in others. This distrust of others, fear of being taken advantage of, fear of one's actions being revealed, and fear of rejection based on one's harmful actions leads to a deep-seated sense of insecurity, which in turn results in loneliness and hopelessness. In the end, this is none other than a state of languishing, the opposite of flourishing, well-being, and positive mental health.

These connections drawn out by the Dalai Lama have gained support not only from basic science, as mentioned above, but also from clinical practice (Gilbert, 2005). In line with this scientific and clinical work, the Dalai Lama goes so far as to say that because we are social beings, a self-centered attitude goes against human nature. This revised view of human nature, with social connection and compassion at its heart, is a refreshing approach to human relations and ethics that could have a profound impact on our societies if taken to heart.

How to Cultivate Compassion

If we accept the mounting evidence in psychology, sociology and the health sciences that positive emotions and values like empathy and compassion show psychological, physiological and social benefits, and if we accept that we have an innate capacity for compassion, then the next important question is whether compassion can be cultivated, and if so, how. Religious traditions appear unified in their suggestion that compassion can indeed be cultivated if actively pursued in the proper way. In a commentary on Geshe Chekawa's "seven-point mind training" instructions, the Buddhist teacher Se Chilbu writes (Jinpa, 2006, p.94):

> Seated on a comfortable cushion, visualize your dear mother vividly in front. First, to cultivate loving-kindness and compassion, reflect in the following manner:
>
> "Because she, my dear mother, first gave me this human existence of leisure and opportunity, which she nurtured without any negligence, I have encountered the Buddha's teachings. Because of this [today] it is possible to grab happiness by its very snout. She has thus helped me. Throughout all stages, when I was in her womb and after birth, she nurtured me with impossible acts of kindness. Not only that, since samsara's beginningless time, she has constantly watched me with eyes of love, perpetually helped me with affection, and repeatedly protected me from harm and misfortune. She has given me so much benefit and happiness and has thus embodied true kindness."
>
> Reflect thus and cultivate a depth of emotion such that tears fall from your eyes and the hairs of your pores stand on end.

There is also a small but growing body of evidence from modern science suggesting that compassion can be enhanced through training, although much more work needs to be done in this area (Lutz et al. 2004, 2007; Neff et al., 2005, 2007, 2011a, 2011b; Pace et al., 2008, 2009). The claim that compassion can be cultivated is furthermore supported by the notion of neuroplasticity, the relatively recent discovery that the structure and function of our brains can be altered throughout adult life through sustained practice. Whereas it may be difficult for animals to cultivate compassion to a high degree, humans have the distinct advantage of having sophisticated cognitive capacities for reasoning and analytical thought, and these capacities can be called upon to enhance our compassion beyond the limited biological compassion that is restricted to persons tied to us by family, ethnicity, religion, and other "in-group" markers, to a larger net encompassing broader and broader sections of humanity, and even animals and the larger environment.

There are doubtless many methods one could employ to enhance compassion beyond the biological level to an impartial altruism, and in fact all religious traditions contain methods for such cultivation. For general purpose applications, however, it is important that the method not be religious in nature, and in fact it need not be. In our studies, we use a protocol for the cultivation of compassion developed by Geshe Lobsang Tenzin Negi, drawn from the *lojong* (Tibetan *blo-sbyong*) tradition of Tibetan Buddhism but rendered into secular form for use by individuals of any, or no, religious inclination. The term *lojong* means "mind training" or "thought transformation" and refers to a practice of gradually training the mind in compassion until altruism becomes spontaneous. This process involves meditation, but whereas meditation on a topic, such as impermanence, takes that topic as a content or object of contemplation, compassion meditation does not take compassion as its object, but rather aims at transforming the mind into a state of compassion: a compassionate mind (H.H. the Dalai Lama, Teaching on Kamalashila's *Stages of Meditation*, Washington DC, July 9, 2011).

The first term lo or "mind" here refers to the complete dimension of an individual's subjectivity, whereas the second term *jong* refers to a complete transformation or reorientation; thus the term *lojong* can be understood as the "transformation of subjectivity," the goal of which is a complete reorientation of the person away from self-centeredness or "self-cherishing" (*bdag gces*) towards altruism or "other-cherishing" (*gzhan gces*), similar to the Christian term *metanoia*.

> *Note 2.* Although the Greek term μετάνοια is typically translated as "repentance," its etymology literally means to change or transform one's mind, and it can therefore be better understood as a fundamental transformation of one's view of the world and oneself beyond current limitations and thought patterns towards a love of others. Understood this way, *metanoia* comes very close to *lojong* in meaning. For more on the "transformation of subjectivity," see Ozawa-de Silva and Dodson-Lavelle (2011).

It is important to note that although individual contemplative practices arise within specific cultural and religious contexts and belief systems, that does not mean that they cannot be adapted and applied outside their original context while still retaining degrees of effectiveness in producing transformations of subjectivity, perhaps because they rely upon cross-culturally applicable embodied cognitive techniques that neither depend upon nor require adherence to metaphysical and philosophical tenets (Gyatso 2001, 2005; Ozawa-de Silva & Ozawa-de Silva, 2010; Varela, Thompson & Rosch 1992; Wallace 2006). Moreover, such practices may retain their efficacy because they address suffering not primarily on a (narrowly conceived) medical model of specific pains, illnesses, and disorders, but rather on an existential level (Ozawa-de Silva & Ozawa-de Silva 2010).

According to the *lojong* tradition, although no one wants difficulties, we still encounter difficulties because of not seeing reality as it is (Gyatso, 2000; Jinpa, 2006). As a result we react to certain perceptions of reality with afflictive emotions such as anger. If we take the time to reassess the situation or person to whom we are feeling anger, and view it or them from another angle, we see that there are also positive dimensions there and our perspective becomes less limited and one-sided. Our anger then naturally diminishes and our mind becomes more peaceful. The key then is being able to investigate reality objectively. Furthermore, *lojong* holds that certain mental states are incompatible and in fact opposites.

Just as increasing the heat in a room naturally reduces the coldness there, or increasing the light decreases the darkness, so does a reduction in anger or hatred create space for compassion, whereas an increase in compassion reduces anger and hatred. Anger and hatred are the motivating factors in violence; nonviolence, it has been pointed out, is not merely the absence of violence, but the manifestation of compassion (Gyatso, 2001; Rosenberg, 2004).

The *lojong* tradition holds that since compassion is the wish to relieve another of suffering, it depends on several things, most importantly (a) perceiving the suffering of another; (b) having a sense of affection or closeness for that person; (c) and recognizing that the suffering can, in fact, be alleviated. If one perceives another suffering, but has no sense of affection for that person, one will either feel indifference to their suffering or one may even take pleasure in their suffering (if, for example, they are viewed as an enemy). On the other hand, when one perceives suffering in a loved one, compassion arises naturally and spontaneously. Just as a lack of affection precludes compassion, so can a lack of insight into suffering. If one has great affection for someone, but one does not realize that they are suffering, one will not feel compassion for them. An example would be having great affection towards a friend who is addicted to cigarettes, but not knowing that nicotine addiction is very harmful to one's health. Lastly, for compassion to be sustainable, one must also have a recognition that the suffering can in fact be eliminated if its underlying causes are removed. If one does not have this recognition, then even if one feels affection towards someone and recognizes their suffering, one's compassion will eventually result in "burn-out" because there it will be replaced with a sense of hopelessness.

Similarly, despite some variation in the emerging literature on compassion, there seems to be broad agreement among scientists that the definition of compassion involves at least the following aspects: a cognitive aspect (recognizing suffering in oneself or another), an affective aspect (a sense of concern or affection for the other), an aspirational or motivational aspect (one wishes to relieve the suffering of the other), an attentional aspect (one's degree of immersion and focus), and a behavioral aspect (a compassionate response; an action that stems from compassion) (Ekman, 2008; Gilbert, 2005; Lutz et al., 2004; Lutz et al., 2008; Neff, 2011a).

Strictly speaking, it seems that the first two are the actual key required ingredients or preconditions for compassion: one must both see suffering in another and have a sense of concern for that other. If both are present, the generation of compassion is a natural result. If either is lacking, compassion is impossible. The fourth (behavior) is therefore actually the result of compassion, namely a compassionate response or an action taken on the basis of having felt compassion. Since this exists in a cause-and-effect relation to compassion, compassionate behavior is not strictly compassion itself; nevertheless such behavior may provide a feedback-effect strengthening or engraining compassion, so it may be an effect that can also become a cause for further compassion. The third, namely the aspirational/motivational aspect, is the actual compassion itself: the wish to relieve the other of suffering. This can range from a weak wish on a highly conceptual level to a powerfully emotional, fully-embodied state. It can also be biased and restricted (biological compassion; biased compassion; limited compassion) or unbiased and universal. Lastly, in addition to the cognitive, affective, motivational/aspirational, and behavioral dimensions, there may be an "attentional" dimension: how focused and stable is one's compassion, or is it merely a fleeting

state of mind, quickly crowded out by one's own emotional distress or various distractions? Additionally, the stronger and more encompassing the affective aspect and the more profound and penetrating the cognitive aspect (suffering can be realized on multiple levels, and goes beyond mere immediate physical and mental pain), the stronger the aspirational and motivational dimension (compassion per se) will be. In other words, genuine full-fledged compassion would contain all five of these dimensions to a high degree.

> **Affective:** How strong is the sense of endearment and affection towards the other? How contrived or conceptual is the state of compassion vs. how fully and physiologically embodied and non-conceptual is it? Is it spontaneous? Is the sense of affection based on bias and partial (friend vs. foe; reciprocal or kin altruism) or is it universal?
>
> **Cognitive:** How profound is the cognitive basis for compassion? What levels of suffering are being perceived? Is it merely immediate physical or mental pain, or does it encompass the causes of that pain, which may extend to deeper structural conditions? Is there a sense of hope based on the recognition that suffering can be ended once its causes are eliminated?
>
> **Attentional:** How sustained and long-lasting is the compassionate state? Is it a fleeting moment, a sustained affective-cognitive state, or a long-term disposition that actually comes to pervade one's daily life?
>
> **Motivational:** Is the compassion merely a wish, a deeply felt aspiration, or even stronger, a fully-engaged and determined motivation to relieve others of suffering? To what extent does the motivation extend to a willingness to sacrifice one's own well-being in order to relieve the suffering of the other?
>
> **Behavioral:** To what extent is it accompanied, followed on by, or reinforced by other behaviors, such as compassionate physical action, compassionate speech or compassionate thoughts (wishes, prayers, aspirations, plans)?

The key to *lojong* practice is therefore cultivating an analytical awareness that counteracts the limited and biased perspectives that result in self-centeredness and deepening that awareness until it becomes a deep-seated altruism that responds spontaneously to the needs of others. To move from a position of self-centeredness to compassion is neither easy nor quick, however. Therefore, a systematic approach is taken that begins from where the practitioner is, and leads him or her step-by-step to the final goal of altruistic, unbiased compassion.

The following outline presents some of the key points taught in CBCT in a sequential and logical order:

(1) experiences of suffering and happiness do not merely depend on external stimuli but on internal mental states (which cause immediate experiences of well-being or suffering when they arise, and which also propel concordant actions that are helpful or harmful to oneself and others, leading to future happiness or suffering);

(2) increased freedom from destructive emotions therefore results in increased happiness and less suffering, both in the short-term (due to not experiencing the destructive emotions) and in the long-term (due to not experiencing the results of harmful actions taken when under the power of destructive emotions);

(3) emotions and other mental states are not permanent but change momentarily and can be transformed with practice;

(4) a strong determination to free oneself from negative emotions helps one to achieve this (self-compassion);

(5) in wanting happiness and to be free from suffering, we and all other beings are alike; there is no difference between us;

(6) we depend on others for everything we enjoy and exist in a web of interdependence with others and the world;

(7) recognizing our sameness with others (5) and how we benefit from them (6) decreases the illusion of distance we feel and leads to a sense of impartiality, gratitude, and affection;

(8) partiality and bias do not only harm those we regard as enemies, but even those we regard as loved ones, since bias is ultimately unjustified and distorts our interaction with others;

(9) when we combine insight into suffering (1–2) with closeness and affection to others (7–8) we recognize that others are suffering and naturally wish for them to be happy, which is "wishing compassion," namely the thought, "How wonderful it would be if they were free from suffering."

(10) when this thought of wishing compassion is strengthened it leads to "aspiring compassion," namely the deeply felt aspirational prayer "May they be free from suffering."

(11) when aspiring compassion is supplemented by taking responsibility for others, and becomes active, it becomes engaged compassion, namely the heartfelt intention "I will do whatever I can to alleviate their suffering."

The process employed in CBCT calls upon and combines two styles of practice taught in *lojong*. The first is the "seven-limb cause and effect" method, which involves principally generating a strong sense of gratitude towards one's mother or another loved one by reflecting upon their kindness (as in the quote by Se Chilbu provided above at the beginning of this section), cultivating that into love and compassion, and then gradually extending that love and compassion towards others. The second is the method of "equalizing and exchanging oneself and others." This involves "equalizing" oneself and others by reflecting on how we are all fundamentally the same in wishing for happiness and wishing to be free from suffering; and how oneself and others are equal in deserving happiness and to be free from suffering. One further reflects on the disadvantages of an excessive self-centered view and the benefits of a view that recognizes interdependence and our need for others and then "exchanges" one's self-cherishing for other-cherishing (see steps 5–8 above). Whereas the

"seven-limb cause and effect" method seems to employ the biological basis of kin altruism to create a platform upon which to cultivate boundless compassion, the "equalizing and exchanging self and other" method seems to employ reciprocal altruism as a basis. Since one method may be more effective for some people than the other, both styles are combined in CBCT. In the end, however, both techniques (and CBCT) intend a universal, unbiased compassion that is not limited to kin or reciprocity.

Furthermore, the fact that each of these stages build on the previous insights in a logical and stepwise fashion has led some of our research team to postulate that CBCT, and the *lojong* tradition that it draws from, employs what we call "embodied cognitive logics." Elsewhere, we have written that "the idea of embodied cognitive logics rests upon the notion that, just as human beings share physical commonalities, we also share mental or psychological commonalities regarding the way we process meaning, affect, and ethical decision making, many of which are rooted in our very embodiment. Furthermore, these commonalities represent an embodied cognitive-affective-moral calculus—that is, a complex and dynamic network of causal relationships that map out the ways a particular embodied cognitive-affective state, once generated, influences other states by inhibiting or promoting them." (Ozawa-de Silva & Dodson-Lavelle, 2011, p. 17–18).

Ongoing Research

The CBCT program explained above is currently being used in a number of research studies in a 6 or 8-week form. The protocol was first employed among a population of undergraduates at Emory University beginning in 2005 to evaluate whether compassion training could be employed as a method to address growing rates of depression in college undergraduates. The results of that study have been published in Pace et al. (2008) and Pace et al. (2009), showing that the practice of compassion meditation reduced neuroendocrine, inflammatory and behavioral responses to psychosocial stress that have been previously linked to the development of mental and physical disease. These encouraging results prompted members of our research team to explore the possibility of employing compassion training as an intervention among younger and older populations.

An NIH grant is funding a five-year Compassion and Attention Longitudinal Meditation (CALM) study, now nearing completion, which is evaluating the CBCT program in an adult population alongside two matched active controls: a second meditation intervention that focuses on attentional training (and not compassion) and a health discussion group. The adult CBCT program is an 8-week intervention that meets for two hours a week. Each session contains pedagogical material presented by the instructors, a guided meditation of around twenty to thirty minutes, and group discussion, with subjects being asked to meditate daily for the duration of the program using guided meditation recordings. The two active control groups follow a similar model, but without compassion-related pedagogy and meditation for the focused attention-only meditation group, and without any form of meditation for the health discussion group.

The CBCT protocol was also piloted in 2008 among adolescents in foster care (ages 13–16) and in 2009 among elementary school children (ages 5–8) in the Atlanta area. These programs followed the same conceptual sequence as the adult program, but with

age-appropriate modifications. In both cases, CBCT teachers from our team went to the children's foster home or school class. For the younger children, classes met twice per week for twenty-five to thirty minutes per session during the normal school day. Classes began with a short meditation practice and a brief overview or introduction to the week's topic, followed by an activity, story, or game to facilitate learning and student engagement. Once we had found an age-appropriate way to convey the topics of the CBCT protocol through such stories and games, we were encouraged to find that even the young elementary-school children were able to grasp the essential concepts involved in the protocol. The methods employed and the results of these pilot programs are described in Ozawa-de Silva and Dodson-Lavelle (2011).

The success of these adaptations has led to on-going studies investigating the effects of compassion training in these populations. In 2010 the Georgia Department of Health and Human Services and the Center for Disease Control in Atlanta, GA funded a randomized, wait-list control trial of CBCT for seventy-two foster children, entitled "A Study of Cognitively-Based Compassion Training (CBCT) to Enhance Health and Well-Being in Adolescents in Foster Care in Metropolitan Atlanta." The study, the results of which have not yet been published, examined the efficacy of this training for reducing emotional reactivity, psycho-social stress, and behavioral problems. Dependent upon the results of the study, the aim is to extend this service throughout the foster care system and to offer similar training programs to foster families, caseworkers, and administrators. On the basis of the pilot program for young elementary school children, our team received a grant from Emory University to run a study using an eight-week long intervention in the 2011–2012 school year at a local school in Atlanta, GA to evaluate the effects of CBCT on prosocial behavior, bullying, social exclusion, stereotypying and bias in collaboration with Dr. Philippe Rochat and Erin Robbins, both of Emory University.

In May 2010 researchers from Emory University and the U.S. Centers for Disease Control and Prevention (CDC) field-tested CBCT in Kosovo to investigate its potential to heal the trauma of war. Based on the success of this trial, a more extensive project is planned for 2012, pending funding, to evaluate CBCT's effects in the treatment of stress and trauma as well as its potential to foster the cultivation of new modes of thinking and behavior that will foster reconciliation and nation-building, thereby reducing the potential for future conflict. The research team includes representatives of Emory, the CDC, the Antares Foundation, and the Kosovo Rehabilitation Centre for Torture. Members of our broader research team at Emory University, including Dr. Nadine Kaslow and Dr. Barbara Patterson, are also investigating the efficacy of CBCT among suicide-attempters at a local hospital in Atlanta and among trauma survivors in Kosovo, and have also begun to explore its application in early-onset Alzheimer's patients and in a prison population.

> *Note 3.* Updates on these projects and links to future publications will be made available at the Emory-Tibet Partnership website (www.tibet.emory.edu) and the website for the Emory Collaborative on Contemplative Studies (www.emory.edu/ECCS/). Additionally, full video footage of presentations on this work at the conference "Compassion Meditation: Mapping Current Research and Charting Future Directions" at Emory University in 2010 with the participation of H.H. the Dalai Lama is available at: www.emory.edu/home/academics/dalailama/visit.html.

Conclusion: The Need for Secular Ethics

Ethical values are indispensable for human happiness and well-being on both an individual and collective level, and this is becoming even clearer as our world becomes smaller and our communities become more diverse. Whereas in the past religion and families played a central role in instilling ethical values in new generations, modern pluralistic and multicultural societies must adapt to the times and find ways to instill ethical values in coming generations in ways that are not partial to one religious tradition over another, or over those who follow no religious tradition. The question of ethics will always be central to religious traditions. In the public square, however, the question of ethics must be separated from the question of religious adherence. New times call for new thinking: if we remain unable to formulate a robust secular ethics, our future well-being, and the well-being of our planet as a whole, may be in grave danger.

Compassion appears to be the most stable foundation for a secular ethics that transcends religious, cultural, and philosophical divides, because it is based on the fundamental human aspirations to have happiness and avoid suffering, because it is rooted in our human nature and our evolutionary heritage, and because it is something that we have the capacity to cultivate individually and socially as human beings endowed with intelligence and reason. Moreover, there is increasing scientific evidence in the fields of medicine, psychology and neuroscience that compassion is not only beneficial for others, but also for oneself. Although this article focuses on one method for cultivating compassion drawn from the Tibetan Buddhist *lojong* tradition, we feel strongly that all religious traditions (and several secular ones) contain methods for the cultivation of compassion, and may serve as sources for the development of secular programs such as the one presented here. Further interreligious dialogue on this issue could prove very fruitful. Much more work in general remains to be done in the area of compassion research, and we hope that this growing subfield attracts more interest given its tremendous potential. Furthermore, since compassion, suffering and well-being pertain to all aspects of our lives, we hope this research will be both truly interdisciplinary in nature and socially engaged.

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YOUNG SCHOLARS' CORNER

The Federal Employees Health Benefits Program: A Model for Health Policy Reform

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Abstract

The Federal Employees Health Benefits Program (FEHBP) is frequently discussed when exploring opportunities for health care reform because of its status as the largest employer-based health insurance program in the United States. The program's unique structure and use of principles of managed competition make it a potential model for reform. It is the goal of this paper to investigate the feasibility, both politically and fiscally, of extending the program to cover the uninsured as well as the potential areas of the program that could be adapted within the private insurance market. Additionally, a comparison will be made between these proposals and those recently passed in the Patient Protection and Affordable Care Act (PPACA) to demonstrate that while there would be significant difficulties in extending the program as it exists today, the program itself has served as a model to help structure health care policy reform.

Keywords: Federal Employees Health Benefits Program, Healthcare Reform, Health Policy, Managed Care, Health Market Competition, Patient Protection and Affordable Care Act

Introduction

When discussing health care reform within the United States, the Federal Employees Health Benefits Program (FEHBP) is frequently cited as a possible model to adopt for Medicare or to extend coverage to the uninsured. Many studies have been conducted to investigate the feasibility of such proposals that have historically been advocated by Presidents, Congressmen and Senators alike. However, drastic expansion of this federally run program, while appealing to many health care reform advocates, would clearly pose operational and fiscal problems for the entire federal government, including Office of Personnel Management (OPM) and the FEHBP itself. There are several specific aspects of the program that have the potential for successful implementation in the private insurance

market, some of which have been included in the recently passed Patient Protection and Affordable Care Act of the 111th Congress.

By examining the operational manner in which OPM administers the FEHBP, and the system design encompassed by the terms managed care and managed competition, possible methods of cost containment within the private insurance market may be illuminated. More specifically, after a thorough examination of the FEHBP and its population, plans and premiums, the reasons behind the program's successes will be better understood, and the lessons more easily applied to the healthcare industry as a whole.

Basic Description

Brief History

The FEHBP was passed into law in 1959 as an attempt on the part of the federal government to recruit employees from the private sector and provide them with an incentive to remain government personnel (Merck, 2003). Coverage initially became available on July 1, 1960, and it has developed into the single largest employer-based health insurance program in the country (Merck, 2003). Private sector employers and labor unions, at the time of FEHBP implementation, were offering health insurance as a benefit of employment. To compete for the most qualified job candidates, the federal government acted not only to provide coverage to its current employees, but to do so efficiently. With such a vast employee pool, insurance risk, and its associated expenses, could be spread to reduce costs of individual coverage.

Methods of Operation

The Office of Personnel Management administers the entirety of the program, from negotiating with nationwide plans on premium prices, to informing enrollees of plan, benefit or premium changes. The OPM's administration cost is covered by a one percent increase to established premium prices (Merlis, 2003). Instead of this management overhead being performed individually by several federal agencies, each specific agency's Human Resource Department, or Benefits Office, acts as a liaison between employer and FEHBP enrollee. Where OPM solely handles annuitants, services such as employee enrollment processes, premium deduction from paychecks, and forwarding employee and agency contributions to OPM, are accomplished through these agency offices (Merlis, 2003). Clearly, the contributions these agencies' human resource offices make to the FEHBP are an area of administrative cost unaccounted for in OPM's budget. These offices work to combine their efforts effectively and conduct massive outreach to the program's eight to nine million enrollees so they become more knowledgeable and make more informed decisions when choosing a plan.

FEHBP as Laboratory

When examining the FEHBP, it is significant to note that the program's unique structure of managing private insurance plans has made it possible for the program to be used as a sort of laboratory for studying the effects of policy on employer-based insurance programs. The federal government's ability to directly influence FEHBP and its policies allows for innovation and progressive policies to be tested for possible reform implications. Since the implementation of this program 50 years ago, few changes have been made to

adapt its structure or drastically change its initial policies, including exclusion limits and extension of coverage into retirement. This fact makes for a stable program, aptly designed for testing smaller initiatives, such as movement away from paper records and towards electronic communication and record keeping ("FEHB-Past Present Future," 2009). Most recently, in the early 2000s, mental health and substance abuse parity, or making these benefits equal to general medical benefits, was made a priority within the program and extensively examined by the OPM (Merck, 2003). Other examples of such experimentation, such as the advocacy for and funding of Health Maintenance Organizations (HMOs) in the 1970s, resulted in the fast growth of such plans within the program ("FEHB-Past Present Future"). The results of these efforts allow for some insight into potential outcomes across the entire market if such changes were to be adopted.

Eligibility, Enrollees and Enrollment

Eligibility Requirements

According to OPM's official website, those eligible for coverage under FEHBP include primarily those employed by the federal government, unless their position is excluded, and also cooperative employees such as those appointed by a federal agency, or those paid in part by non-federal funds (U.S. Office of Personnel Management F). The full list of eligible federal employees can be found on the OPM website, but also includes various entities such as acting postmasters, presidential appointees, U.S. Commissioners, and Agricultural Stabilization and Conservation County Committee employees (U.S. Office of Personnel Management E). Federal employees excluded from coverage consist of non-citizens, those who work for the District of Columbia, Tennessee Valley Authority, Farm Credit Administration, administration-supervised corporations, patient employees, and those paid on a contract or fee basis (U.S. Office of Personnel Management E). Additionally, civilian employees on active military duty, such as reservists, are able to retain their coverage while deployed (U.S. Office of Personnel Management E). Retired employees are also able to enroll in the program, as long as they had been enrolled in the immediate five years preceding retirement. Officially, OPM has absolute and final say in determining eligibility into the program. Thus the primary eligibility requirement is related to employment in the federal government, as the program's name implies.

The FEHBP is perhaps most well-known for its coverage of members of Congress, the President of the United States, and coverage of their specific staffs. The argument over expansion, or adoption, of the program to cover the growing number of uninsured, has frequently been based on the populist idea that, "What is good enough for our leaders should be good enough for everybody else." It is this same premise that brought about, under the Patient Protection and Affordable Care Act, the shift of coverage of this population from FEHBP to the insurance exchanges created by the Act, which will be discussed in further detail later in this paper.

Also qualified to enter the FEHBP are the spouses, former spouses, surviving spouses and dependents of employees. Adult children are covered up to the age of 22, which may be extended if that individual is "incapable of self-support" due to an injury or preexisting condition existing before the age of 22 (U.S. Office of Personnel Management F). Along with PPACA reform, coverage of adult children was extended to age 26 on

January 1, 2011, even if the adult children lost coverage before this reform (Spurway, 2010). This is distinct from the extension of coverage to adult children on private insurance plans, which occurred on September 23, 2010, and is an example of policy applicable to private plans being applied to federal plans as well. In general, OPM's descriptions of "spouse" and "dependent" seem to be wide-ranging and generous. However, there has been slight controversy over OPM policy, and federal law, under the Defense of Marriage Act, which states that same-sex spouses are not eligible for coverage under the FEHBP, even in states where these marriages are legally recognized (U.S. Office of Personnel Management G).

Population of Enrollees

Roughly 85 percent of federal employees participate in FEHBP (Bovbjerg, 2009). While this does not differ greatly from enrollment rates in the private sector, the number of people covered by the program far surpasses that of any other employer in the country. Over the past decade, the population of insured within the FEHBP stayed in the range of eight to nine million persons, generally remaining around 8.5 million (Merlis, 2003). As of 2003, 4.1 million of these were policy holders, i.e., persons of primary eligibility based on federal employment, making approximately 48 percent of the covered population employees, 2.2 million of whom are currently employed by the federal government while the remaining 1.9 million are retired (Davis, Cooper, & Capasso, 2003). The majority of people enrolled within the program, 52 percent, are spouses and dependents covered by the policyholder's plan. Unlike the private sector, where the average age of enrollees is 37.4, the average age of those enrolled in FEHBP is 47 (Quincy & Williams, 2009). Of the 1.85 million retired enrollees, about 83 percent were over the age of 65, making FEHBP a supplemental policy to their Medicare coverage (Davis, Cooper, & Capasso, 2003). Those retired, but under the age of 65 and not eligible for Medicare, around 314,500 people, are the highest cost population FEHBP covers (Davis, Cooper, & Capasso, 2003) (Table 1).

While not much supplemental information beyond the age and gender of those covered under FEHBP is available, it is safe to say that this specific population of employees is less likely than others to have lower income (Davis, Cooper, & Capasso, 2003). This not only means that higher-quality plans are more economically feasible than for most groups, but that plans with lower than standard benefits options are potentially unnecessary to include in the market. While this phenomenon has not been specifically studied under the FEHBP, having plans with a minimum standard of benefits, although they are not specifically required by OPM, and no "free-choice" plan, drastically reduces the effect of adverse risk selection within a specific market (Enthoven, 1989). Additionally, one tenth of those enrolled in the program reside near the Washington DC metropolitan region (Davis, Cooper, & Capasso, 2003). With drastically smaller

Table 1. The FEHB Program: 2008 Basic Facts

Employee Policyholders*	2,159,533
Average Annual Premium (single coverage)	$5,037
Average Age of Policyholder	47
Distribution by Plan Type	
Preferred Provider Organizations (PPOs)	71%
Health Maintenance Organizations (HMOs)	27%
Other**	2%

Source: Consumers Union Report, July 2009, "Basic Facts about the Federal Employees Health Benefit Program" by Lynn Quincy and Bob Williams. Data from Office of Personnel Management, 2009.

*Approximately 3 million dependents and 3 million retired enrollees bring the total covered to over 8 million.

** "Other" plan type includes Consumer Directed Health Plans and High Deductible Health Plans.

populations of federal employees located in more rural areas of the country, access points for specific plans can be over an hour's drive away (Merlis, 2003). This highly concentrated population in the DC metropolitan area tends to mitigate overall measures on access such as those noted by The Kaiser Family Foundation study conducted by Merlis, in which access to primary care providers for Lebanon, Kansas, as a prime example of rural enrollment, showed that enrollees there must drive over an hour to receive in-network care (Table 2).

Table 2. Access to In-Network Primary Care for Resident of Lebanon, KS, FEHBP National Plans, 2003

	Number of in-network primary care physicians within:				Minimum distance for in-network primary care:	
Plan	**15 miles**	**16–25 miles**	**20–35 miles**	**36–50 miles**	**Mileage**	**Driving time**
Alliance	0	0	0	1	42.8	1 hr., 3 min.
APWU	0	0	0	1	42.8	1 hr., 3 min.
Blue Cross	7	15	3	25	14.8	20 min.
GEHA	0	2	1	5	20.6	26 min.
Mail Handlers*	0	0	0	1	42.8	1 hr., 3 min.
NALCa	0	0	0	1	42.8	1 hr., 3 min.
Postmasters	0	0	0	1	46.4	1 hr., 10 min.

*Use same PPO network.

Note: Primary care physicians include family and general practitioners, internists, pediatricians, and obstetricians/gynecologists.

Source: Based on online provider directories accessed April 8, 2003. Mileage and travel times estimated using Microsoft Streets & Trips 2001.

Source: The Henry J. Kaiser Family Foundation, May 2003. "The Federal Employees Health Benefits Program: Program Design, Recent Performance, and Implications for Medicare Reform." Mark Merlis.

Enrollment Procedures

Upon becoming employed by the federal government, an individual has up to 60 days to decide whether or not to enroll in FEHBP (U.S. Office of Personnel Management D). The same length of time is also provided to make changes or enroll in the program after a major life event such as a marriage, birth or death (U.S. Office of Personnel Management B). However, there is an annual "Open Season," usually beginning in November and lasting for a month, where anybody can enroll, cancel, add to, or adjust their plans, whether it is general coverage, vision, dental or Flexible Spending Accounts (FSA) (Merlis, 2003). The process of changing plans is significantly less complicated than in the private market with the annual Open Season opportunity and many federal agencies offering online enrollment (U.S. Office of Personnel Management C).

To accommodate a plethora of plan options, OPM distributes an annual guide to its enrollees to assist in their knowledge about available plans (Merlis, 2003). This guide provides not only the premium price for each plan, but its service area, cost-sharing requirements, and satisfaction survey results (Merlis, 2003). Supplementary brochures, describing specific benefits and other information concerning individual plans, can be found online or at each agency's benefits office (Merlis, 2003). In terms of innovative information dissemination, OPM's website offers the ability to easily click and compare different plans

offered in the program. Additional information from private sources is also available to potential enrollees in the form of guide books, such as *Washington Consumers' Checkbook*, which are sometimes provided to employees by federal agencies (Merlis, 2003).

Managed Care and Competition

The successful functioning of a large health benefit program, such as the FEHBP, depends on two organizational principles: managed care and managed competition. These two principles, in conjunction with a knowledgeable, cost-conscious consumer, and motivated program sponsor, or manager, allow for reduction of potential market failures and inequalities that are often seen in the private insurance market.

Managed Care

Frequently cited as an effective cost-containment measure in health care, "managed care" involves structuring the organization of the medical practice. Specifically, managed care directly links financing and the provision of care (Enthoven, 1989). By putting into place quality control measurements and then matching resources and personnel to the served population, there is a reduction in both redundancy and inefficiency throughout the system (Enthoven, 1989). By utilizing the methods of managed care, costs can be reduced by 28 percent while still producing the same output and providing the same care (Enthoven, 1989).

The FEHBP relies on certain managed care measures such as the use of a primary care physician as a "gatekeeper" to necessary medical procedures or specialists (Rinn, 2001). The program also attempts to focus on the use of networks of physicians and providers to maximize the efficiency and quality of care (Rinn, 2001). An example of such a network would be a Comprehensive Care Organization (CCO) that consolidates all the necessary ingredients for proper care of more expensive diseases or disorders, such as cancer, in one location. While these organizations are not extensively used in the FEHBP, they are certainly highly advocated for by the program and OPM itself as it attempts to provide this form of care on a smaller scale.

Managed Competition

The second method by which OPM attempts to contain the costs, compared to the relatively inefficient private insurance market, is by creating a system using the rules of managed competition. In this system, private health plans are encouraged to compete, under rules of microeconomic principles, to provide maximum value to both consumers and employers (Enthoven, 1989). The OPM's official function is to, "design and actively manage a process of informed cost-conscious consumer choice" and "to motivate managed care plans to produce a favorable combination of efficiency and equity" to achieve value of money paid for services received and equality of payment into the system (Enthoven, 1989).

The methods used by OPM to manage the market do not go far enough, some argue, to provide the maximum reduction of costs, but have proven to assist in avoiding inequalities and failures seen in the private insurance market, such as segmentation and risk selection (Gray & Selden, 2002). Some of the managed competition tools include negotiating premium prices in FFS plans, deciding which plans are included in the market,

and providing a capped subsidy to employees, which will all be examined further in the paper. As previously discussed, OPM and its affiliated agencies combine efforts to inform their enrollees about the market and its available coverage plans in order to have a more cost-conscious, knowledgeable consumer (Enthoven, 1989). According to theorists, such as Enthoven, the success of managed competition depends on both the active manager and cost-conscious consumer moving the market in the direction of greater efficiency and equity, linking cost and provision of care.

Plans and Premiums

Plans Offered

According to OPM, Open Season 2011 has 207 plans available from which to choose (U.S. Office of Personnel Management A). While there is no mandated standard benefit package required by OPM in the FEHBP, the majority of plans offer a broad selection of basic services, including inpatient and outpatient hospital care, ambulance service, physician and surgical services, as well as diagnostic tests and emergency care (Merck, 2003). Prescription drug coverage, however, has been a required benefit since 1990 in all plans made available in the FEHBP and is paid for, in part, through low levels of enrollee cost-sharing (Merck, 2003). At first glance, the number of plans may seem to provide an abundance of options but many of the options are really affiliated with specific regional health maintenance organization (HMO) plans resulting in an estimated 100 distinct organizations with oversight capacity (Merlis, 2003).

Nevertheless, the plans offered by the FEHBP can be categorized into "government wide," or national, policies and regional plans (Merlis, 2003). Government-wide plans tend to be fee-for-service (FFS) based plans, and provide coverage to over two thirds of the enrollee population (Davis, Cooper, & Capasso, 2003). The most populated plans offered in the FEHBP, the standard and basic options of Blue Cross Blue Shield FFS / Preferred Provider Organization (PPO) plan, cover nearly 50% of those in the program (Davis, Cooper, & Capasso, 2003). A PPO, essentially areas of predetermined consolidated care through loosely affiliated network providers, offers lower out-of pocket costs to those going to see an in-network provider (Davis, Cooper, & Capasso, 2003). Unfortunately, not all areas have easy access to PPO providers, making this element of a plan unfeasible for some employees depending on where they reside (Merck, 2003). The majority of these national FFS plans have a PPO element, especially those offered by employee organizations (Davis, Cooper, & Capasso, 2003). There are 12 plans offered by such organizations, six of which are exclusive to their employees, such as the United States Postal Service plan and the plans for those involved in Foreign or Secret Service (Davis, Cooper, & Capasso, 2003). One of the most significant aspects of these FFS plans is that they tend to attract more of the retired, more expensive, population, with 84 percent of retirees participating in PPOs compared to 62 percent of active employees (Davis, Cooper, & Capasso, 2003).

Regional plans offered by FEHBP tend to be HMO and point of service (POS) plans (Davis, Cooper, & Capasso, 2003). Only about 25 percent of enrollees choose to opt into HMO plans, essentially meaning the majority of plans serve a minority of enrollees (Davis, Cooper, & Capasso, 2003). There have been instances where specific HMO plans will drop out of the FEHBP market due to lack of enrollment and uncompetitive premiums

(Merck, 2003). Overall, this has not been much of an issue, as only around 1 to 5% of those enrolled are affected annually by HMOs leaving FEHBP (Merck, 2003). In essence, HMOs are able to participate in the FEHBP as long as there are no limits on enrollment concerning age, sex or health status (Merck, 2003).

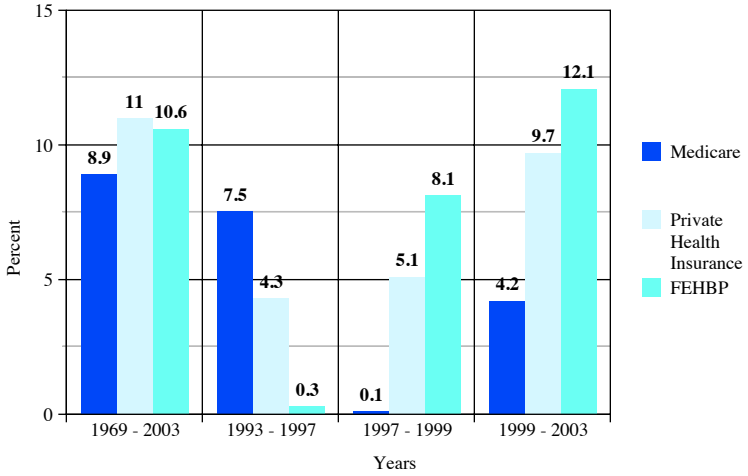
Payment Methodology

One of the most interesting aspects of the FEHBP is its unique payment system. It is in this area that the federal government is able to contain costs and prevent many of the market failures seen in the private insurance market from afflicting the program. Where most employers cover close to 70% of the average family premium cost, the FEHBP has a subsidy cap in place (The Henry J. Kaiser Family Foundation A). This subsidy from the federal government covers 75% of the premium, up to a capped amount, below national plan premiums or 72% of the average premium, weighted by enrollment (Merlis, 2003). Regardless of the plan chosen, employees must cover at least 25% of their premium price (Merlis, 2003). However, there is an exception to this rule for Postal Employees, who have outside negotiations with OPM to determine a lower portion of the premium cost they must cover (Merlis, 2003). If an employee chooses a plan with a higher premium than most, they cover up to 28% of the average premium cost, and the additional difference between that and the price of their own plan (Davis, Cooper, & Capasso, 2003). This helps to explain the large portion of enrollees choosing lower-cost plans, which has the potential of forcing more expensive, and comprehensive, plans out of the program (Davis, Cooper, & Capasso, 2003).

Similar to the private insurance market, there are two add-ons to the price of the plan's premium. However, these additional price increases do not raise the cost of the premium as significantly. First, there is the 1% surcharge to cover the administration costs incurred by the OPM (Merlis, 2003). It is interesting to note that the true operating costs of the OPM are actually much lower than this, at about one tenth of one percent of total expenditures in 2000 (Merlis, 2003). The remaining funds are then deposited into reserves, for which there is an additional 3% increase in premium rates covered by both the enrollee and their employer (Merlis, 2003). This money is then deposited in the U.S. Treasury into a FEHBP trust fund, as well as a Retired Employees Health Benefits (REHB) fund, and is further identified as individual plan or general plan reserves (Merlis, 2003). The purpose of these reserves is to remove fundamentally financial risk from the plans. If the cost of the plan surpasses its premium fees, or there is an unexpected large increase, or too much fluctuation in premium prices, then funds from these reserves may be used to cover these expenditures (Merlis, 2003). Historically, these reserves have never been completely depleted but were made significantly smaller in the 1990s and have since been replenished, which explains a portion of the premium increases at the onset of the decade, as can be seen in Figure 1 (Merlis, 2003).

Premiums

Premiums in the FEHBP are distinctive because of the fact that no risk-adjustment is involved in determining their price. All members of a specific plan pay the same premium regardless of age, race, gender or health status (Davis, Cooper, & Capasso, 2003). Premiums for national plans do not vary by location either, spreading the risk across all regions of the country (Merlis, 2003). There are two different methods in the FEHBP for determining premium prices, depending on whether the plan is nationally or regionally rated.



CMS, Office of the Actuary 2002, Medicare, Private Health Insurance (PHI), and Medicaid (not including SCHIP) spending: FEHBP 2003.

Figure 1. Change in spending per enrollee, Medicare and other purchasers selected years.

Nationally rated plans, or the FFS/PPO plans, generally use the experience-rating method for setting premium levels (Merck, 2003). This means that each plan's expected costs for FEHBP enrollees in the upcoming year are taken into account, to which a "service charge," a roughly 1% increase, is added (Merlis, 2003). The expected cost takes into account both the population being served, as well as expected inflation and other factors that may influence the cost of an individual plan (Merlis, 2003). Premiums are then negotiated between OPM and the individual provider in order to ensure a fair price that is directly connected to the cost of expected services provided (Merlis, 2003). Traditionally, OPM uses these negotiations to call for the addition or removal of specific benefits from specific plans in an attempt to control for adverse risk selection or market segmentation. Increased plan similarity was the outcome of these efforts, ultimately resulting in the standard plan options from the Government Employees Health Association (GEHA) and Blue Cross Blue Shield in the early 2000s (Merck, 2003).

Unlike national plans offered in the FEHBP, regional HMO plans are not subject to negotiation with the OPM in setting premium levels (Merlis, 2003). These plans use a community-rating method, which involves each plan providing premium costs for two employers, of a similar size plan that they cover, to OPM (Merlis, 2003). The lower of these two premiums is then set as the "community rate" within the program, which is then subject to change based upon the expected use of services and technology by the FEHBP population (Merlis, 2003). Also differing from nationally rated plans, these premiums are more likely to reflect demographic differences within the population being served (Merlis, 2003) (Figure 1).

Between 1969 and 2003, premiums in the FEHBP increased 10.6%, which is slightly less than those in the private insurance market, but higher than increases in Medicare spending (Davis, Cooper, & Capasso, 2003). These increases are largely due to overall medical inflation and consistently increasing prescription drug and medication costs (Davis,

Cooper, & Capasso, 2003). However, the ability of the program to influence premium costs has lessened the impact relative to the rising premium costs seen within the private market, but to relatively less extent than Medicare, which is able to set payments to healthcare providers for individual visits and procedures (Davis, Cooper, & Capasso, 2003).

Quality Assessment

Quality assessment and consumer satisfaction are of the utmost importance to the FEHBP because of their large impact on the cost and effectiveness of the program. For each of the plans offered, an annual survey is undertaken to obtain information about enrollee satisfaction (Merlis, 2003). The results of these surveys are then made easily available online to everyone choosing or comparing different plans within the program (Merck, 2003). These "report cards" not only assist enrollees in deciding on a coverage option, but aid OPM in negotiating with insurance providers and choosing which plans to offer (Merlis, 2003). Additionally, for a plan to be considered for offering within the FEHBP, it must be fully accredited and meet specific requirements for the OPM population (Merlis, 2003). To be considered a nationally rated plan in the FEHBP, a carrier must be licensed to sell health insurance coverage in every state, while local and regional plans must be licensed in the states where they function (Merck, 2003). HMOs, on the other hand, must meet additional specific requirements such as having provider credentials, maintaining internal quality assurance programs within their structure, and compiling and analyzing patient outcomes for specific conditions (Merck, 2003).

One of the integral requirements for the successful functioning of the FEHBP is the knowledgeable consumer, reviewing options to ensure competition between the plans. OPM, in conjunction with the federal agencies, strives to ensure this is a reality. On an annual basis there is an FEHBP Guide made available by OPM with descriptions of the different plans offered, their premiums, as well as what they require in terms of co-payments, waiting times, and locations of care (U.S. Office of Personnel Management H). It is clear the program desires its enrollees to be knowledgeable about all potential benefits and forms of coverage, as the guide also describes different dental, vision, and long term care plans as well as Federal Flexible Spending Accounts (U.S. Office of Personnel Management H). Extensive outreach to enrollees occurs in preparation for each Open Season, which includes OPM's annual letter describing any changes in benefits or premium costs (U.S. Office of Personnel Management A). As previously mentioned, there are also private sources of information available to those interested, such as the *Washington Consumers' Checkbook*, which is sometimes provided by the enrollee's employer (Merlis, 2003).

Issues with FEHBP

Despite a myriad of efforts by the federal government to manage competition amongst the plans offered in the FEHBP, there remain historical, and continuing, issues with the program and its true level of effectiveness. These issues, while present within the private health insurance industry, manifest themselves slightly differently in the FEHBP as there is a clear "sponsor" directly influencing the market. Furthermore, it should be noted that these issues within the program are directly related to the proper functioning and existence of the program, and have, in the past, manifested a threat to the continuation of the plan itself.

Adverse Selection

First and foremost is the historical struggle within the program against adverse risk selection (Davis, Cooper, & Capasso, 2003). Adverse risk selection within a market is related to the availability and expansiveness of choice of plans, in that sicker populations of enrollees tend to choose plans with more benefits, and therefore higher premium costs (Davis, Cooper, & Capasso, 2003). This leaves the majority of people within the program with a decision between cross-subsidizing higher cost populations within more expensive plans, or settling for fewer benefits than desired to avoid cost (Davis, Cooper, & Capasso, 2003). When low-risk individuals avoid the cross-subsidization of high-risk enrollees, both efficiency and equality within the program are affected in that some do not receive the coverage they desire, while others are left paying more for their plans (Gray & Selden, 2002). This, most significantly, can create an environment that potentially fosters a spiraling cycle of rising premium costs within more generous plans, eventually forcing them out of the market entirely.

Recently in the FEHBP, adverse risk selection has not proven to be extensive as a complication or issue. This problem has mostly manifested within the "high" plan options, such as Blue Cross/ Blue Shield and Aetna, the national fee-for-service (FFS) plans, where many retired enrollees turn for coverage (Feldman, Thorp, & Gray, 2002). It has been posited in numerous studies, however, including those done by economists such as Gray and Selden, that the subsidy cap in place in the FEHBP has the effect of curbing adverse selection among plans. Because the number of plans in the program is already restricted, in comparison to the private market, and the program uses a fixed subsidy cap, this form of risk selection has, the majority of the time, been successfully avoided (Gray & Selden, 2002). As a subsidy cap rises, higher-cost plans benefit the most as the largest of these subsidies goes towards plans with more expensive enrollees, enacting a sort of roundabout form of risk adjustment (Gray & Selden, 2002). However, since the FEHBP utilizes a capped premium subsidy, incentives for competitive consumer shopping among plans are maintained, while adverse selection remains low (Gray & Selden, 2002).

Segmentation

While the issue of adverse risk selection among plans within the FEHBP has seemingly been reduced over time, segmentation of populations across the program undoubtedly remains. As previously discussed, the overwhelming majority of enrollees choose the standard FFS Blue Cross/Blue Shield plan, leaving around one third of the population within the program to choose among the remaining options. The option to choose other than the standard and basic FFS Blue Cross/Blue Shield plans, while in and of itself not a large issue, represents a potential trend of reduced competition within the program, especially among HMO plan options (Davis, Cooper, & Capasso, 2003).

Reduced Competition

Historically, the FEHBP has not suffered from a dramatic number of plans leaving the program. The attrition tends to affect regional HMO plans as the total number of HMOs in the program has dropped from 428 in 1998 to 159 in 2003 (Merlis, 2003). The vast reduction in plans may partially be due to plan consolidation and mergers throughout the years (Merck, 2003). Plans that do decide to leave the FEHBP market generally drop out due to insufficient

enrollment and noncompetitive premium prices (Merck, 2003). It has also been suggested that HMO plans have been unsuccessful in predicting service utilization and risk of enrollees from the program (Merck, 2003). Regardless of the factors behind low enrollment figures for these plans, the number of individuals affected by HMOs dropping out of the FEHBP is around 1 to 2% of the population, or 5% of those enrolled in HMOs (Merck, 2003).

The 1989 exodus from the national Aetna FFS plan is frequently and consistently noted as having resulted from adverse risk selection issues within the FEHBP (Hustead, 1997). While Aetna was not able to meet the negotiated premium price set forth by OPM, and subsequently withdrew from the program, enrollment in this plan was one of FEHBP's highest (Hustead). This could clearly indicate the presence of a more expensive, sicker population within the plan. It has been alternatively posited however that Aetna was simultaneously dropping all of its FFS plans, and OPM's market authority was a "convenient excuse" to leave the program (Francis, 2003).

Expansion or Adaptation for the Uninsured?

Although healthcare reform has recently been passed by the 111th Congress, it is important to examine properly the advantages and disadvantages of using the model of the FEHBP to extend coverage to the increasingly large population of uninsured individuals throughout the country. In the past, proposals have been offered to expand the program to both the uninsured and small business populations, e.g., President Clinton's proposal of voluntary purchasing cooperatives for small businesses, Senator Bill Bradley's position of expansion during his campaign for President in 2000, and Representative Pete Stark's "Health Insurance for All Americans Act of 1999" (Fuchs, 2000).

Both extension of the program and adoption of a similar model to cover these populations will be appraised.

Advantages

Little Disruption to Private Market

If a similar model to the FEHBP, or the program itself, were to be used to provide coverage to Americans, there would be minimal disruption to the private insurance market (McArdle, 1995). Since the program incorporates existing private plans there would be no need for the creation of a public option or other government run plan, which insurance companies would clearly oppose. Additionally, persons currently receiving adequate health care coverage in the private market would not need to switch plans, preserving satisfactory provider and enrollee relationships (McArdle, 1995).

National Plans

The use of nationally rated plans in the FEHBP provides an opportunity to reduce regional differences in premium prices, especially for those negatively affected with more unhealthy and expensive populations (McArdle, 1995). This would also provide a more

expansive array of plan options from which to choose, including some that are available within every region (McArdle, 1995). The existing network of these plans provides an easy, reliable way to extend coverage to non-federal employees because of the administrative structure currently in place, whether the FEHBP is expanded or a similar model is used (McArdle, 1995). The large pooling of small business employees, for example, could drastically reduce high premium costs currently affecting small businesses, an issue which has been forcing some to drop or reduce health care coverage for their employees. Increased competition among plans, in this manner, could potentially bend the curve on rising premiums as well.

Disadvantages

Population Issues

As previously discussed, there are many population differences between federal employees and those who could potentially be granted coverage if the program were to be expanded. These differences would not only impact the overall affordability of plans within the program, but potentially the types of plans available as well. Specifically, federal employees tend to be wealthier, meaning they have more expendable income and can therefore afford more generous health care plans. Low-income individuals opting in to the FEHBP would most likely need further subsidies and financial assistance from the federal government in order to afford their share of the premium (McArdle, 1995). Since more generous plans might decide to leave the program, bringing in ones offering less coverage that would be more affordable for this new population of enrollees, this could essentially lead to massive disruption of plans available within the market.

Impact on the Federal Budget

The subsidies necessary to cover the low-income uninsured population would clearly have a large impact on the federal budget. While the federal government has already been concerned over the rising costs of the FEHBP, adding millions of individuals to the program whose premium would also be subsidized by OPM would drastically increase the overall cost of the program (Feldman, Thorp, & Gray, 2002). However, in the plans proposed by government officials to expand FEHBP, separate risk pools for incoming populations were included as an attempt to reduce disruption to those currently enrolled in the program.

Eligibility and Adverse Selection

Because plans in the FEHBP do not deny coverage based on an individual's level of risk, those with preexisting conditions would be able to find affordable coverage. While this is definitely a positive aspect of the program, if it were to be extended to other populations there is the risk that an overwhelming amount of those with preexisting conditions or comorbidities, who tend to be the most expensive population to cover, would enroll. If healthy individuals did not enroll at the same rate, FEHBP runs the risk of adverse selection leading to spiraling premium costs, forcing plans out of the market.

Disruption to FEHBP

The disadvantages previously discussed would clearly pose a disruption to those currently enrolled in the FEHBP. Unless the format of the program were used as a model for a similar federally run market for non-federal employee civilians, it is obvious that those in the FEHBP would find the results of the expansion unacceptable. Additionally, the culture of public service among federal employees is of significance in that the benefit of the FEHBP is seen as a sort of supplementary form of compensation as these employees are generally paid less than if they worked in the same positions in the private market. The expansion of this benefit to the private civilian workforce would not only seemingly diminish the value of service of federal employees, but would seem to provide a much larger benefit to new enrollees as their amount of expendable income would rise as well.

Access Issues

The problem of easy access to in-network providers in rural areas has already been discussed. However, it is significant to point out that a large number of the uninsured population tends to be both low-income and reside in rural areas. If PPO access points for these populations require an hour or more of driving, coverage becomes far more expensive due to travel costs, and far less accessible, especially if frequent visits to their primary care provider are necessary.

FEHBP and PPACA

The issue of healthcare reform was a topic of the highest priority to the Democrat controlled 111th Congress, witnessed by the recent passing of the Patient Protection and Affordable Care Act. In the deliberations concerning this issue, the FEHBP was considered as a model for reform but quickly discarded due to federal employee discontent and overall unattractiveness of the idea in terms of the federal budget. However, there remain numerous elements of the bill that seem to adopt aspects of the FEHBP.

Pre-existing Conditions

One of the most popular aspects of PPACA is the stipulation that insurance companies not turn down coverage for an individual based on the presence of pre-existing conditions. All people eligible for coverage in the FEHBP with pre-existing conditions are accepted into the program as risk is effectively spread across a large pool of enrollees, avoiding high premium costs. It is questionable, however, how this will affect the private insurance market and whether or not the addition of this expensive population will drive up costs, especially with the individual mandate portion of the bill. It was thought that by requiring all individuals to purchase insurance, the risk pool would be large enough to have a similar effect as in the FEHBP, but the reality of this theory has yet to be proven.

Health Insurance Exchanges

As part of PPACA the federal government created state-based insurance exchanges where individuals and small businesses of up to 100 employees may purchase coverage beginning in 2014 (The Henry J. Kaiser Family Foundation B). States are also able to

create regional exchanges, helping spread risk across a slightly broader geographical area (The Henry J. Kaiser Family Foundation B). These exchanges are required to guarantee renewability and premium rating variation based only upon age, tobacco use and other family factors (The Henry J. Kaiser Family Foundation B). Differing from the FEHBP, risk adjustment is required in these exchanges (The Henry J. Kaiser Family Foundation B).

OPM's Role

Interestingly enough, OPM plays a significant role in these insurance exchanges, in that it is now required to negotiate with insurers to provide at least two multi-state plans within each exchange (The Henry J. Kaiser Family Foundation B). This allows the federal government some input in determining the plans available within the exchanges. These plans, however, will operate separately from the FEHBP and have a distinct risk pool thus having no direct effect on the FEHBP itself (The Henry J. Kaiser Family Foundation B). There are restrictions and requirements for these plans as well, in that one must be from a non-profit provider and one cannot cover the cost of abortions beyond what is permitted by federal law (The Henry J. Kaiser Family Foundation B).

Abortion Coverage

Plans offered within these exchanges, just like the FEHBP, are not allowed to use federal funds to cover abortions (The Henry J. Kaiser Family Foundation B). States that choose to allow plans with abortion coverage must create separate "allocation accounts" to separate and distribute premium payments into the exchange for coverage of abortions (The Henry J. Kaiser Family Foundation B).

Subsidies

It is clear, as in the discussion about expansion of the FEHBP, that to ensure the enrollment of uninsured individuals, especially those who are healthy, generous subsidies would need to be provided. According to PPACA, the federal government will provide premium credits up to 400% of the Federal Poverty Level as well as cost-sharing subsidies (The Henry J. Kaiser Family Foundation B). These credits and subsidies provided to eligible individuals and families will be tied to the second lowest cost "silver" plan in the exchange on a sliding scale (The Henry J. Kaiser Family Foundation B). Premium contributions for these enrollees will increase annually to reflect premium growth as compared to income growth until 2018 when this sliding scale will be properly adjusted (The Henry J. Kaiser Family Foundation B).

Consumer Protections

Similar to the FEHBP, there is a large emphasis on knowledgeable consumers within these markets. There will be a website with search options to assist individuals in finding an appropriate health plan, with information about each of the plans made readily available (The Henry J. Kaiser Family Foundation B). Standards for the dissemination of information, and the format of information concerning benefits and coverage, will also be

standardized to reduce confusion and ensure that consumers are able to easily distinguish the differences between plan options (The Henry J. Kaiser Family Foundation B).

Primary Care and Preventative Services

Finally, PPACA places a large emphasis on the use of primary care physicians and preventive services to improve the quality of healthcare in the United States, as well as increase system performance (The Henry J. Kaiser Family Foundation B). While the emphasis on primary care takes place largely within Medicare, because the federal government is able to exert more control over this area of the market, it is hoped that this emphasis will spill over and influence the private insurance industry. Similar to the use of primary care physicians, PPACA only requires the use of preventative services in federal programs such as Medicare and Medicaid (The Henry J. Kaiser Family Foundation B). The emphasis on preventative care is not only manifested in incentives to complete "behavior modification programs" but in the creation of wellness programs in small businesses, funded by federal grants, and the legalization of employee rewards for participating in such a program and meeting health-related standards (The Henry J. Kaiser Family Foundation B). These rewards may include premium discounts, cost-sharing requirement waivers, and additional benefits (The Henry J. Kaiser Family Foundation B).

Conclusion

While the FEHBP provides a unique model to examine cost containment measures and the successful use of managed care and managed competition, it is apparent that extension of the program would encounter significant limitations in application to the uninsured. However, it remains a positive example of a largely successful employer-based healthcare coverage program, and many of its tenets have been adopted in the design of the PPACA. The role of the federal government through OPM and its negotiations with insurance companies illuminates a currently acceptable method of government intervention which provides the opportunity to influence private industry through policy innovation on the part of government.

PPACA and other recent efforts towards healthcare reform have been achieved through incremental change to the system, with the first priority being coverage of the uninsured. This has significantly increased cost requirements at both federal and state government levels as coverage depends on both the expansion of Medicaid and federal credits and subsidies up to 400% of the Federal Poverty Level. With this new funding requirement on the part of federal and state governments, it will be in their best interest to implement further methods of cost containment. Policy makers and other government officials can examine the FEHBP's use of principles of managed care and managed competition to reduce program costs across the market, especially within the private insurance industry.

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DEPARTMENT OF THE NAVY
UNITED STATES OF AMERICA

COMMENTARY AND REVIEWS

On Being a Black Scientist: Personal Reflections on the Tuskegee Syphilis Experiments

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Author Note

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Introduction

Despite growing up in an inner-city surrounded by poverty and economic disparity in the 1970s, becoming a physician was a career goal that appeared within my reach. But, at the time, the delineation between physicians and scientists was not so clear to me. Learning the scientific method and participating in science fairs seemed like an exercise in scientific thinking and a modest outlet for artistic skills. Even though I grew up in a violent and tumultuous time when our nation was emerging through the civil rights movement and other socio-cultural revolutions, the revelation that physicians, as scientists, could perform experiments on human subjects was a revolutionary concept for my naive mind.

In 1972, the horrors of the Tuskegee Syphilis Experiment became headline news. The fact that 399 syphilitic black men were left untreated for 40 years in efforts to study the natural history and complications of syphilis was shocking to many (Jones, 1981). Now, nearly 40 years since the Associated Press broke the news to the world, the Tuskegee Syphilis Experiment is still a cautionary tale vivid in the minds of many. Many American blacks are painfully aware of this infamous clinical study, and the fact that the U.S. government was the primary perpetrator is rarely lost on anyone. As time moves forward, the impact of this particular tragedy—an unconscionable act against a vulnerable group—is still evident. Other well-documented accounts of abuses in the name of research and medical care exist, but the events in Tuskegee, AL, seem to overshadow even our most egregious contemporary cases.

My life and medical career in infectious diseases virtually spans from the timing of the public exposure of the Tuskegee experiments. Several of my close elder relatives vividly remember the anger they felt during the earlier years of debate and discourse about the study.

More often than coincidence, casual conservations or encounters during active recruitment sessions with other blacks to engage in research trials (including therapeutically) end with "I don't want to be a guinea pig."

A Legacy of Mistrust

During a recent visit to a clinical trial evaluating the safety and tolerability of an investigational vaccine, a volunteer (black male) expressed to me his mistrust of other members of the research team. Being the only black physician, he confided in me his complete medical history (e.g., depression). Although he had undergone an extensive informed consent process and had volunteered understanding the potential risks of study participation, he feared speaking honestly with white physicians. He attributed this fear to the white Public Health Service doctors mistreating blacks during the Tuskegee study. I could not dismiss his fearfulness as irrational, but reassured him that stringent protections were in place to prevent such abuses from ever happening again. Thereafter, this man only wanted to see me at his study visits.

Paradoxically, I often wondered if this volunteer was aware that Nurse Eunice Rivers and Dr. Eugene Dibble, among others, were highly respected blacks who had been hired as key personnel in the conduct of the Tuskegee study annual round-ups and performance of autopsies (Jones, 1981). Why did they not object to the study? Were they also misled? Could I ever be so misguided in conducting research or contributing to a collaborative project?

It was documented that some personnel involved in the study were not informed of the complete facts (Jones, 1981). They thought treatments given were similar to the preceding campaign to combat syphilis. Nurse Rivers was fully aware that the men were only getting placebos and did not to receive a full course of the current standard treatment. Further, she clearly understood that the men were not to receive penicillin when it became available. As a study nurse, she admitted to following the orders of the doctors and never questioned their actions. I believe the study doctors relied upon her community standing to convince the men that the study procedures were valid and justified.

From the 1930s to the late 1960s, objections to the experimental procedures from Nurse Rivers or any woman would have likely resulted in termination and little initiative to change course. Presently, the courage to question a superior could remain challenging for any individual, but easier because of whistleblower laws and other protections. Subordinates are now more empowered to help protect others from potential mistakes or harmful experimental procedures.

Of course, the experiment itself was never a secret among the mainstream medical community, but clear understanding of the ethical implications (allowing men to die when effective treatment was readily available) was apparently not appreciated. Some conject that "group think" intertwined with racism allowed the study to continue uninterrupted or challenged. The individuality of the men was never a consideration as the study was passed from investigator to investigator. A scientific question took precedence over the lives of real people –who were powerless, undereducated, poor, and black.

The roots of such mistrust likely penetrate deeper than Tuskegee as blacks and other minorities have experienced many other instances of injustices (socially, politically, economically, etc.). Across the U.S., major health disparities continue despite modernization and widespread availability of high quality medical care for those with access to it. For instance, a recent surveillance report shows that the rates of syphilis infections, now combined with HIV/AIDS, remain disproportionately higher among black and Hispanic men who have sex with men (MSM) (Su, Beltrami, Zaidi, & Weinstock, 2011; Mayer & Mimiaga, 2011). Not surprisingly, the emergence of HIV/AIDS has created an environment where additional discriminatory practices (i.e., based upon sexual preferences) can exist within healthcare and medical research.

The near absence of blacks participating in research clinical trials is not totally unimaginable. The fears of abuse and neglect are derived from actual events. Washington (2006) provides a thoroughly intense and frank examination of historical facts of unethical medical experimentation extending across the historic landscape of America from life on plantations to modern times.

Research studies performed abroad have also been riddled with shameful behaviors in the name of science. The discovery that U.S. researchers infected Guatemalan prisoners and mentally ill patients with syphilis and other venereal diseases in the 1940s adds to the legacy of mistrust. This uncovering of blatant unethical conduct confirms that the Tuskegee experiment was likely not an isolated occurrence. It only begs us to pose the question: where else has this occurred? And why? If not because of pure racism against black Americans, then could such acts abroad represent an exertion of power and the ability to dehumanize any race of people for some scientific objective?

Hope for Change

Some 40 years beyond blatant abuses, researchers face tough regulations and potential imprisonment for maltreatment of research subjects. Institutions face disruption of entire research programs, loss of credibility, prestige and funding. It could be argued that without the exposure of the Tuskegee experiments, the status quo would have continued harming other vulnerable populations and many more people. The events literally changed the course of human subjects research for all Americans.

Even though a few changes in the regulations have evolved, they can be seen as a complex milieu that inexperienced and seasoned investigators can easily find overwhelming. Attempts at preparing a clear and concise informed consent written in lay terms can become clouded by legal clauses included to protect the institution instead of the research volunteer. Despite these challenges, it is clear that researchers cannot operate in a vacuum of the past and attempt to conceal risks or exaggerate benefits.

In a broader context within the black community, the historic election of the first African American U.S. President has been a dream fulfilled. It fuels hope for more changes in all aspects of life, including improvements in access to affordable healthcare and equity in medical breakthroughs provided via research.

Conclusions

Despite being monumental, I believe these barriers can be crossed by fostering responsibility, and placing focus on caring research inclusive of minorities and other vulnerable groups. In addition to adhering to high professional standards of trust, researchers should be imbued with an ability to care. Similarly physicians performing research among their established patient population must remain cautious of therapeutic misconception when conducting trials, but patients should still be able to trust that their physician will "do no harm."

Many want to believe that the Public Health Service began the Tuskegee experiment with good intentions aimed at bringing awareness to a significant health problem in a rural isolated community. Somehow their noble efforts became eroded into unnecessary suffering that could have been prevented.

In our current climate of multi-centered trials and collaborative partnerships, many scientists and their mammoth teams of research professionals could easily lose their way—and not care about people. Caring aside—neglecting our responsibility to respect persons, protect the rights of individuals and avoid harm could lead us down the path to further mistrust of the scientific community.

As a black scientist, I humbly accept the enormous responsibilities I face daily protecting the rights and welfare of every individual (regardless of their ethnicity, gender, nationality, etc.) within or connected to my purview. And caring is a personal and professional core value.

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Book Review

The Price of Indifference: Refugees and Humanitarian Action in the New Century (2002) Arthur C. Helton Oxford University Press, 314 pp.

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Review

With the most recent humanitarian crisis in East Africa competing, often unfavorably, with the global economic crisis, domestic U.S. politics, and ongoing unrest in the Middle East for our collective attention and resources, one may reasonably ask "what should the U.S. do?" For health care professionals, military service-members, and supporting non-governmental organizations the response typically is "everything we can." But is this the appropriate response? How do we adjudge which crisis gets our attention and resources? What practical things can be done to alleviate human suffering in an era of constrained resources?

In his 2002 book *The Price of Indifference: Refugees and Humanitarian Action in the New Century*, Arthur C. Helton, a Senior Fellow for Refugee Studies and Preventative Action at the Council on Foreign Relations in New York provided just such advice to both policy makers and those charged with carrying out those policies. The work stands today as a definitive treatise on refugee issues in the conduct of foreign policy. The reader is treated to clear prose and direct recommendations on "why refugees matter," "the last decade's refugee story," and "imagining better refugee policy" among other related topics.

In his chapter "Reaction and Inattention within the U.S. Government" Helton critiques U.S. policy in the humanitarian-heavy decade of the 1990s.Many of his suggestions for interagency cooperation on humanitarian action have been attempted. His criticisms of both Congress and the Executive Branch still have resonance.

Perhaps no chapter in the book has weathered the test of 21st century reality better than "Imagining Better Refugee Policy." While the scenario analysis method he recommends to prepare leaders for any contingency is used in small intra-agency circles, it has by no means been employed by the larger system of inter-agency response teams. Helton's proposals for international cooperation, containment, and proactive policy can still be used as educative tools for policy makers and practitioners if the dates for "future" actions are simply moved forward by a decade.

While nearly a decade has passed since the writing of *The Price of Indifference*, the essence of the matter has scarcely changed. In fact, one could argue the past decade of conventional and counterinsurgency warfare has merely shelved the policy debate concerning the treatment of refugees and humanitarian aid policy. Humanitarian commitments have continued during the past ten years—the Navy's primary recruiting slogan has since changed to the humanitarian evocation "A Global Force for Good"—yet it can be argued that the U.S. was better prepared to execute complex, large-scale humanitarian assistance operations in 2000 than it is in 2012. Hard-won skills in specialized logistics delivery, NGO coordination and integration, and inter-agency cooperation have atrophied with a decade of uninterrupted kinetic operations. The U.S. military has been honed to a near-perfect warfighting edge often at the expense of humanitarian assistance competencies. Many will argue this is not true of certain narrow communities within the Department of Defense, but on the whole this fact is undeniable.

The real solutions lie in part with the policy of the United States. As the mission winds down in Iraq and our commitment in Afghanistan is substantially downsized, policy decisions must be made to enhance the humanitarian assistance capabilities of our military. The blueprint for the creation of effective policy can be found in Helton's timeless recommendations. Even without the "benefit" of the past decade's experience, *The Price of Indifference* represents a tremendous resource for practitioners as well as interested people of conscience. It is not the stand-alone source on these matters.

Ultimately, this is a book only about policy. Helton states "the book is aimed at a policy audience, but is designed to appeal to both general and expert readers…" It is that non-policy wonk, general or expert reader who may be left somewhat unsatisfied. There are far deeper philosophical questions to be answered about our duty to alleviate suffering in far-off lands. Those deeper questions are answered more effectively when approached philosophically. Stanley Hoffman's *The Ethics of Politics and Humanitarian Intervention*, George Lucas' *Perspectives on Humanitarian Military Intervention*, and James Turner Johnson's *Morality of Contemporary Warfare* provide far more thorough coverage of why we should care. Helton tells us, primarily, how we should formulate policy to address the need. He invokes the famous Richard Holbrook retort to "why do refugees matter? Because they're there" as a short cut to his practical recommendations. This can be unhelpful, perhaps even counterproductive, to the policy audience as well as the general and expert reader. I suggest reading Hoffman, Lucas, or Johnson before *The Price of Indifference*.

The "general and expert reader" will also demand a greater explanation of how improvements are to be made at the tactical level, or the point at which policy is executed. The policy audience should be made to understand the implications of their proposals.

Helton suggests lessons from past crises can be applied a *priori* to future crises—strange considering the defining event of the decade he describes, Somalia 1992–1993, provided so few principles for subsequent humanitarian and refugee operations in the former Yugoslavia. As General Anthony C. Zinni, USMC (retired), former Commander of U.S. Central Command, Operations Director of Operation Restore Hope in Somalia 1992–1993, and commander of Operation United Shield in Somalia in 1995 has stated publicly many times, policy is but a first, albeit a critical step in humanitarian assistance planning and execution. Defining political objectives and an exit strategy are as important in humanitarian assistance of refugees as they are to conventional warfare. But Zinni and many others have also claimed the military is generally ill-prepared to do these missions well. Wars in Iraq and Afghanistan have only exacerbated this issue. Seldom read doctrine such as Joint Publication 3-29 *Foreign Humanitarian Assistance* (FHA) is actually quite well written compared with most doctrinal publications and provides the most practical of guides for those tasked with policy execution. It may surprise many that such doctrine is also aimed at general and expert readers and is almost as valuable to non-military personnel involved in FHA as military. The U.S. Agency for International Development and Department of State has equally readable doctrine for FHA. *The Price of Indifference* is essential as an unflinching review of past mistakes and flawed assumptions and should precede any reading of U.S. government doctrine.

The Price of Indifference is not without additional flaws. Critics have charged Helton with being somewhat naïve in his suggestions concerning budget decisions. Many argue we do not currently possess the luxury to shift limited resources away from counter-terror and counterinsurgency. There is some validity in that viewpoint given the predicted defense budget. Others will argue the international dynamic has rendered many of his recommendations concerning "state building and refugees" obsolete. Perhaps those awarded fellowships by the American Society of International Law named in honor of Helton would do well by updating and expanding his work. There can be no greater testament to the ideals articulated in *The Price of Indifference* than to develop an expanded edition for the second decade of the 21st century.

In the end, *The Price of Indifference* remains as important today as it was when initially published. It should be read by "general and expert readers," particularly practitioners, and acted upon by policy makers. For all those audiences it should be augmented by deeper considerations of our duty as a nation. When read in tandem with more philosophical texts, a clear picture of the nature of humanitarian assistance and why the U.S. should move forward to meet crises is available. When considered in conjunction with the publications of those activities that make humanitarian assistance possible, the next decade of U.S. policy initiatives becomes clear. All agencies of the federal government should dedicate time and resources to this fundamental international duty.

Commission Report Review

"Ethically Impossible" STD Research in Guatemala from 1946 to 1948 (2011) Presidential Commission for the Study of Bioethical Issues, 206 pp.

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Introduction

Between 1946–1948, the United States supported and conducted medical research involving sexually transmitted diseases (STDs) in Guatemala. Until recently, many of the details of this research were unknown; however, as more facts were discovered, a deeply disturbing picture of the research subjects' treatment appeared. To understand the historical context and actions of the researchers involved, as well as to review modern human subjects protection, President Barack Obama directed the Presidential Commission for the Study of Bioethical Issues to conduct a retrospective fact-finding investigation in combination with a detailed review of current regulations and international standards of human subject protection. The Commission began its work in January 2011 and decided to bifurcate its findings into two reports. The subject of this review is the first report, a historical account and ethical assessment of the experiments conducted in Guatemala.

Synopsis

STDs were already a longstanding concern of the U.S. government, military medicine, and the public health community by the time research began in Guatemala in 1946. At the start of World War II, doctors were still using the same system of chemical prophylaxis for STDs as in World War I. The National Research Council estimated that new gonorrhea infections in the military could account for 7,000,000 lost days per year and cost the equivalent of $440 million in today's economy. These staggering estimates highlighted a critical need to develop appropriate STD prophylaxis and led to an increase in funding for the study of medical problems (such as STDs) that had the potential to impact national defense.

The Commission Report begins by providing background information on research that served as a precursor to the Guatemala experiments and identifies key differences in the treatment of research subjects between the experiments. Four years before the research began in Guatemala, university-based researchers proposed experiments involving intentional exposure to the bacterium that causes gonorrhea, *Neisseria gonorrhoeae*. After discussion at the National Research Council (NRC) Subcommittee, it was decided that official government backing should be secured. By the end of 1942, the Surgeons General of the Navy, Army, and Public Health Service all supported the research with a proviso that only volunteers be used for the study. Although the use of volunteers allayed some concerns, the permissibility, both ethical and legal, of intentional exposure in humans remained unclear to many at the time. The Commission Report carefully details the populations considered for these experiments, noting that both soldiers and psychiatric patients were proposed as subjects, but quickly dismissed. The former because they could neither be isolated sexually nor given time off from military service for the experiments, and the latter because they were incapable of providing voluntary consent for the experiments.

Ultimately, it was decided that prisoners in state prisons and city jails were best suited as research subjects because they were under medical supervision and isolated from women, and therefore able to abstain from sexual intercourse for a set period of six months. Researchers also believed that prisoners, many of whom had previously contracted gonorrhea, were less likely to be concerned about the risks of participation. In September 1943, at the United States Penitentiary in Terre Haute, Indiana, researchers began intentionally infecting subjects with gonorrhea through artificial exposure. Five months into the experiment, researchers found that they were unable to consistently produce gonorrhea infections in the volunteers and the project leader felt that further efforts were unlikely to succeed. The Terre Haute experiments concluded 10 months after they began, leaving unanswered the questions of whether any prophylactic agent in use actually had preventative value and how to reliably produce gonorrhea in test subjects through artificial exposure.

Faced with the difficulty of reliably producing infection through artificial exposure during the Terre Haute experiments, researchers began to consider opportunities to study infection rates after "normal exposure," or sexual intercourse. A variety of factors led to the decision to relocate STD research in Guatemala. At the time, the United States and Guatemala had an established relationship that involved aid for medical and public health services, as well as for United States medical researchers already working there. Guatemalan physicians were sponsored to study as fellows at the Venereal Disease Research Laboratory (VDRL), where they worked side by side with United States researchers. While on his fellowship at the VDRL, Guatemalan physician Dr. Juan Funes proposed the idea of conducting STD research. Given the legality of commercial sex work in Guatemala, researchers believed that controlled studies could be conducted in which volunteers were exposed to infected prostitutes. Commercial sex workers were required to undergo regular health inspections at designated medical facilities managed by the Guatemalan Venereal Disease Control Department, which Dr. Funes directed. U.S. Surgeon General Thomas Parran approved the research grant and project researchers arrived in Guatemala in August 1946.

The Commission Report carefully details the experiments, both serological and intentional exposure, conducted in Guatemala. In November 1946, researchers began to use serology testing to confirm the presence of antibodies against STDs, evaluating the

effectiveness of four different blood tests. Over the span of the serological testing, four groups of subjects were tested: prisoners, children, leprosy patients, and psychiatric patients. Although researchers planned to proceed with prophylaxis research after the serology testing, they found a lack of cooperation among the prisoners, many of whom believed that frequent withdrawals of blood weakened them. In addition to blood testing, the psychiatric patients also underwent lumbar punctures and cisternal punctures for serological purposes. Despite testing over 2,900 subjects in the serology experiments, there is no evidence that any of the subjects consented to the procedures.

In February 1947, researchers began the intentional exposure and prophylaxis experiments. Between February 1947 and October 1948, 1,308 subjects were involved in the intentional exposure experiments. Subjects for these experiments included prisoners, psychiatric patients, commercial sex workers, and soldiers. The original research proposal indicated that the experiments would test the orvus-mapharsen wash after prisoners were exposed to infected sex workers, to determine whether the wash was effective as a prophylaxis for syphilis. After encountering difficulties in obtaining compliant subjects, as well as trouble diagnosing syphilis and reliably inducing infection, the original experiment was never conducted. Instead, researchers moved beyond their original question, broadening the scope of the research.

Researchers conducted intentional exposure experiments involving three STDs: gonorrhea, syphilis, and chancroid. The Commission Report brings to light details in each of these experiments that are deeply troubling. The gonorrhea experiments were largely conducted using Guatemalan soldiers as subjects and commercial sex workers as the source of infection. There is no evidence that the soldiers gave consent for the experiments. In the case of the sex workers, researchers artificially inoculated several with gonorrhea, but records do not indicate that the sex workers consented to the experiment or even knew that they were infected with STDs by the researchers. Further, records show that several sex workers were given alcohol prior to the experiments.

The syphilis experiments were intended to study the clinical efficacy of the orvus-mapharsen wash, which was previously proven effective in rabbits, as prophylaxis. Researchers used rabbits as the source of most of the strains of syphilis for these experiments. Unbeknownst to several of the commercial sex workers engaged in the syphilis experiments, researchers inoculated them with rabbit testicular syphilomata through intra-cervical injection. Subjects for these experiments included prisoners, psychiatric patients, and commercial sex workers. Again, there is no evidence that the subjects consented to participate in the experiments. Further, the researchers viewed prisoners who were indigenous Guatemalans as uneducated, and documents reflect that researchers believed it unnecessary to explain the experiments to these subjects. Records indicate that not only did some prisoners object to participation, but also that researchers intentionally deceived the prisoners about the research goals.

Unlike the research conducted in Guatemala, the Commission successfully humanizes the subjects' experience by providing subject profiles throughout their report. One subject profiled is Berta, a psychiatric patient who was injected in her arm with syphilis. Despite developing red bumps at the injection site and lesions on her arms and legs, she was

not treated for syphilis until three months after the injection. As Berta's health deteriorated, a researcher noted that she appeared as if she was going to die. On that same day, the researcher put gonorrheal pus into both of Berta's eyes, urethra, and rectum. In addition, he re-infected her with syphilis. Four days after, Berta died.

Understandably, the researchers' supervisors raised concerns about conducting intentional exposure experiments using psychiatric patients as subjects. In one instance, a supervisor stated that he was concerned about the experiment with the "insane people as they cannot give consent and do not know what is going on..." Concerns were raised about negative public reaction and at least one recommendation was made to eliminate reference to the location of the research and the type of volunteer or subject used.

Psychiatric patients were also exposed to syphilis by means of a cisternal puncture. This procedure involved injecting syphilis into the spinal fluid from the back of the skull, in an attempt to determine whether the "blood-spinal fluid barrier" could prevent syphilis from entering the central nervous system. The subjects selected for inoculation through cisternal puncture were previously diagnosed with epilepsy, and researchers desired to test whether the inoculation would ameliorate epilepsy in these patients. At the time of the experiment, the result of injecting infectious material into the cerebral spinal fluid was unknown. In addition, researchers did not consider cultural concerns about this type of procedure, despite colleagues identifying cultural superstitions. Researchers reported that patients who underwent cisternal punctures were given a reward of two packs of cigarettes.

The Commission Report identifies pervasive concerns about secrecy throughout these experiments. In February 1947, Surgeon General Parran, who had approved the grant for this research, expressed continued interest in the progress; however, he also commented that experiments of this nature could never be performed in the United States. Shortly after the Surgeon General's comment, *The New York Times* science editor, Waldemar Kaempffert, published a note regarding the success of penicillin when administered to rabbits shortly after syphilis exposure. Kaempffert noted that the quickest way to determine whether penicillin would also work for humans would be to inject syphilis into humans, but concluded that this would be "ethically impossible." Kaempffert's note was published in May 1947 and yet, the experiments in Guatemala continued through December 1948.

After completing the historical review, the Commission evaluates the researchers' actions against a framework of three ethical principles. The first ethical principle is that "one ought to treat people fairly and with respect." By failing to obtain consent, intentionally deceiving subjects, and not providing additional safeguards for vulnerable populations, the researchers in Guatemala placed their work above the human subjects involved in these experiments. In their failure to consider the interests of their subjects, researchers violated the principle to treat a human subject with respect.

The second ethical principle against which the Commission evaluates the researchers' actions is that "one ought not to subject people to harm or risk of harm, even with their consent, unless the risk is reasonable and there is a proportionate humanitarian benefit to be obtained." The experiments in Guatemala placed the subjects at unacceptable risk through the use of poorly designed experiments, failure to provide treatment, and the use

of procedures against which the researchers' supervisors advised. The subsequent alteration and excision of data demonstrates again that the researchers did not adequately protect their human subjects, but rather focused on their desired results even to the exclusion of appropriate scientific methods.

The third and final ethical principle is that "one ought not to treat people as mere means to the ends of others." The actions of the researchers and governments involved clearly indicate that the human subjects were used as mere means. The documents reviewed by the Commission repeatedly indicates that subjects objected to participation, were deceived about the nature of the experiment, did not give consent, or were subjected to procedures that were not adequately assessed for risk to the subject. Such violations of human dignity are appalling.

Conclusion

The details of the Guatemala experiments shock the reader's conscience. Whether the researchers' actions are measured by current standards and practice or their own, the Commission Report clearly identifies ethical violations. There is no evidence that informed consent was obtained from individual subjects, and in some cases, subjects were intentionally deceived about the purpose of the experiment. Vulnerable subject populations, such as minors, prisoners, and mentally impaired patients, were not afforded any protection. Although psychiatric patients were ruled out as subjects in the Terre Haute experiments, these patients were used in nearly every experiment in Guatemala. By limiting outside knowledge of the research, there was little opportunity for independent review of research protocols, leaving the researchers' conduct unchecked. Even as contemporaneous media deemed such experiments "ethically impossible," researchers in Guatemala did not heed the warning. Instead, they pulled the cloak of secrecy even tighter. Certainly the researchers bear moral responsibility for their actions; however, blame falls beyond the individual. The institutions and governments involved also bear responsibility for the experiments that occurred in Guatemala. Even more broadly, this tragic history underscores the moral responsibility of each citizen in each nation to uphold the dignity of human persons against all other influences. Through the reprehensible actions detailed in this historical tragedy, we are all reminded of the privilege to work with human subjects and the tremendous responsibility to preserve their dignity. The Commission's work reminds us that we must work only within the realm of what is ethically possible.


DEPARTMENT OF THE NAVY
UNITED STATES OF AMERICA

THE POETS' CORNER

Light Years

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We each sit in excessively comfortable chairs. We lounge more than sit. The chairs are cleaned with exacting care and are fragrant-free. The chairs remind me of those in old-time beauty parlors that had hair dryers, like astronaut helmets, that sounded like vacuum cleaners. As a seven-year old, I always hurried past these beauty parlors, worrying that I would be dragged in for some inexplicable reason.

Ironically, the first time I was ever in a hair salon, as they are now called, was when I was twenty years old and actually, for the very first time, getting my hair washed, styled, and blown dry. Generally, my mother would cut my hair at eleven o'clock at night when I was asleep in my bed.

Most of the persons sitting in these very comfortable chairs have no hair. Some are wearing self-styled bandanas. Others wear baseball hats and skullcaps, like football players wear under their helmet. Each patient is being infused with what they hope will save their life. Some patients are chatting with the one sitting next to them. Some are sleeping. Others read books, do the crossword, eat the lunch they brought, or watch the television on the other side of the room. The TV is closed-captioned so as not to disturb those not interested. It is much like being on an afternoon train. There is no standing room, however.

Intermittently, patients struggle from their chairs, unplug from the wall socket the machine that is dripping into them the curing (in some cases) chemicals, clutch the pole, and wheel themselves into the bathroom. Most people idly lift their heads to observe this slow procession.

It is generally very cold in the communal patient room. This is for reasons I do not know and don't care enough about to ask. I always come prepared, even in summer—long pants, closed-toed shoes, long-sleeve blouse, a sweater. I am armed with a spellbinding mystery and water in a phthalate-free container. There are cookies, crackers, and assorted juices that are available and of no interest to me.

Patients talk with registered nurses as if there is no one else in the room, though there are fourteen of us. They laugh, make jokes between themselves, and discuss side-effects of the therapy that they are receiving. It is a very private conversation, though we are its captive audience. While this is going on, other patients become respectfully deaf. It is like waiting outside a confessional. Whatever is said in this room is considered secret and sacred, though there is no edict written on a white board at the departure door. The silence amongst us is understood.

The registered nurses are Archangels. They should be exalted and given the jewelry of cardinals. They should receive Wall Street salaries.

The oncologist called two days before Christmas to tell me of his diagnosis. After a beat or two, my response was, "We expected that." By "we," I meant he and I.

I had been sitting on our front patio with my husband and twenty-year old son. When I emerged from my home office, my face was stone-white. They asked what the phone message was, and I said that an acquaintance had been in a car accident and thankfully, had only minor injuries.

I waited a year to tell my husband of my diagnosis. I waited, I suppose, because I did not want to burden him with this "thing." I did not want it to be the elephant in the room with conversations and questions always centered on my health and therapies. Also, I preferred the idea of doing it on my own. Not without medical doctors and treatments but creating within myself the courage and strength, like running a marathon, to meet this disease head-on. I did not want fuss and drama and over-wrought compassion.

I receive my treatments once a week now, versus the twice-a-week regimen I had been receiving. It was during one of these sessions that I met a woman in the adjacent chair. For some reason, she found me very funny. Light-heartedly, she began to mimic my comments, which I, in turn, found funny. She told me that she has pancreatic cancer. Her aunt, the fourth chair over, also has pancreatic cancer.

She is half Navajo and half Apache. I like that—Warriors. The nurse adjusts the infusion, and then comes to me and says that she will be giving me a "push," which means that therapy will be gently and steadily pushed into my intravenous line, which feeds into the port in my chest. When she brings over the syringe, I always read the label and look at the syringe to be sure it is filled with the correct dose. It always is, of course. In fact, two nurses stand in front of each patient and read aloud the patient's name, the name of the medication, and the dosage they are about to administer. Their checks and balances far surpass anything Congress could concoct or follow.

The Navajo-Apache woman asks the name of my condition, and I whisper it so low that she asks me to repeat it. For some reason, I treat this "thing" as something that need not be discussed. It is not interesting or important, like a flat tire that was repaired last week. It is too vulgar and incidental to assign the medical name to it. This way, I must think, it will not take hold of me, nor will it conquer me.

Oftentimes, I forget I have this thing. Each Wednesday morning, my husband will say, "Good luck with *the stuff*." We have agreed not to give the drug its name. By refusing to name the lifesaving drug, the disease is fooled into believing, I think, that it has no impact on my life. Most people would undoubtedly call this denial. I call it the power position, a kind of arm wrestle, which I believe that I am winning. I expect to experience this thing caving in, giving up, looking somewhere else to roost.

Murphee, the rescue dog, who is now a staff member, is accompanied by John. They both went through rigorous screening and training. Murphee stops at the open door and scans the room. I smile, and both she and John stroll to me. I reach down to pet Murphee. Her coat is black and glistening, her eyes clear and interested. She smiles, too, in her own unique way and reaches up to lick any part of my body, preferably my face. I lean farther over, Murphee gives me a loving swipe, and I feel a tugging at the infusion needle that is embedded in the port in my chest. I pull back and push aside my blouse. The needle is still safely entombed in the first layer of my skin that overlaps the port.

The Navajo-Apache woman has awakened. It is Indian summer now, though the leaves are struggling to change from green to yellow. The sun is strong, and the flowers continue to bloom. Freshly washed laundry and pet toys hang on outdoor washlines. The woman asks my name. I tell her, and she tells me hers. Then, I ask her what her Native American name is, and she tells me that her tribes do not disclose this to anyone but other Natives. I suggest a name for myself. She offers an alternative: Golden Spirit Eagle.

The End

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